Appeal No. 13-16833

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, ET AL.,

Plaintiffs-Appellants,

v.

ALAMEDA COUNTY, ET AL.,

Defendants-Appellees.

On Appeal From the United States District Court
for the Northern District of California
Case No. 3:12-cv-06203-RS

APPELLEE'S BRIEF

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INTRODUCTION

The United States Supreme Court has consistently instructed courts to defer to the judgment of duly elected local legislators who promulgate laws designed to protect local residents' health, safety, and environment. The deference paid to local government is particularly pronounced in the area of waste disposal, which the Supreme Court recognizes to be typically and traditionally a local government function.

Recognizing the local health, safety, and environmental problems created by unwanted or abandoned prescription drugs, the Alameda County Board of Supervisors passed the Alameda County "Safe Drug Disposal Ordinance" (the "Ordinance") in July 2012. The Ordinance requires all pharmaceutical "Producers" (defined below as manufacturers and others) that sell, offer for sale, or distribute prescription drugs in Alameda County to establish and fund a program for the collection and disposal of unwanted and abandoned prescription drugs.

Appellants are three trade associations representing the pharmaceutical industry: Pharmaceutical Research and Manufacturers of America, Generic Pharmaceutical Association, and Biotechnology Industry Organization (collectively, "PhRMA"). PhRMA filed the subject complaint against Alameda County and its Department of Environmental Health (collectively "Alameda County," "Alameda," or "County"), challenging the Ordinance as unconstitutional

under the dormant Commerce Clause, which prohibits discriminatory local economic protectionism designed to benefit local businesses over substantially similar non-resident competitors.

Based on the "Stipulated Facts," the parties brought cross-motions for summary judgment in the District Court. Alameda demonstrated that the Ordinance is constitutional because it is not protectionist, does not discriminate in favor of in-County competitors against substantially similar out-of-County competitors, does not act like a tariff, does not require any conduct outside of the County, does not directly regulate interstate commerce, will not inhibit the flow of commerce, and has *de minimis* costs as compared with its stipulated important health, safety, and environmental benefits. As a result, the District Court correctly granted Alameda's motion and denied PhRMA's motion "[b]ecause the Ordinance does not discriminate against out-of-state actors in favor of local persons or entities, and does not otherwise impermissibly burden interstate commerce, . . ." ER 1-11 at 2 [Order Denying Plaintiffs' Motion for Summary Judgment and Granting Defendants' Cross-Motion ("Order")].

In order to claim unconstitutional protectionism under the Commerce Clause, PhRMA argues on appeal that the Ordinance discriminates in favor of Alameda County and its residents and against Producers. However, because the County and its residents, on the one hand, and in-County and out-of-County

Producers, on the other hand, are not "substantially similar" entities within the meaning of Commerce Clause jurisprudence, the Ordinance does not unconstitutionally discriminate. Absent prohibited protectionist discrimination, the Supreme Court has consistently upheld incidental burdens on interstate commerce arising from local regulation.

In addition, PhRMA argues that, because Producers sell their products into the County through a large scale national distribution system, Alameda may not hold them responsible for the costs, burdens, and risks that their products impose on the health, safety, and environment of Alameda's residents. However, the United States Supreme Court has already determined that the pharmaceutical manufacturers' national distribution system does not insulate them from local regulation.

PhRMA also complains that the distribution system chosen by the manufacturers impedes their own ability to recoup from Alameda consumers the costs incurred in complying with the Ordinance. But no dormant Commerce Clause case has held a regulation unconstitutional because compliance costs could not be recouped by a point-of-sale or point-of-disposal fee. Similarly, no case supports PhRMA's assertion that the Commerce Clause prohibits a local government from shifting its costs to regulated entities, provided all substantially similar entities are treated equally, as they are under the Ordinance. Indeed,

contrary to PhRMA's suggestion, the dormant Commerce Clause is not intended to protect companies' profits.

The Stipulated Facts and Supreme Court and Ninth Circuit precedents compel the conclusion reached by the District Court that the Ordinance is a valid exercise of Alameda County's police power and does not violate the dormant Commerce Clause. Because PhRMA cannot meet its high burden of proof that the incidental burden imposed on interstate commerce "is clearly excessive in relation to the putative local benefits," the Ordinance is constitutional. *See Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). Accordingly, the District Court's decision should be affirmed.

JURISDICTION, STANDARD OF REVIEW AND STATEMENT OF THE CASE

Alameda concurs with PhRMA's Jurisdictional Statement and Standard of Review. Alameda generally concurs with PhRMA's Statement of the Case.

ISSUES PRESENTED

1. Whether Alameda County's "Safe Drug Disposal Ordinance" is an incidental, non-discriminatory burden on interstate commerce under the dormant Commerce Clause, as found by the District Court.

2. Whether the District Court correctly applied the standard set by *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970), in concluding that the incidental burden on interstate commerce imposed by Alameda County's "Safe Drug

Disposal Ordinance" is not clearly excessive relative to the stipulated local environmental, health, and safety benefits.

STATEMENT OF FACTS

I. Alameda County's Safe Drug Disposal Ordinance.

Unwanted, unused, or abandoned prescription drugs are a growing public health, safety, and environmental problem in Alameda. ER 62-63 [Declaration of Nathan A. Miley in Support of Defendants' Cross-Motion for Summary Judgment ("Miley Decl."), ¶ 2]. As the Ordinance declares, "There is no mandatory statewide drug stewardship program for unwanted drugs in California, and drug manufacturers and producers have not offered any support for a permanent collection program to date." ER 64-80 at 65 [Exhibit A to Miley Decl. ("Exhibit A") (Alameda Health and Safety Code § 6.53.010.D)].

On July 24, 2012, the County Board of Supervisors addressed this pressing issue by adopting the Ordinance, despite strenuous opposition from the pharmaceutical industry represented by PhRMA. ER 64-80 (Miley Decl., Exhibit A, §§ 6.53.010 *et seq.*). The Ordinance fills the void in California law by "requir[ing] that manufacturers of prescription drugs who sell, offer for sale, or distribute prescription drugs in Alameda County . . . operate and finance a product stewardship plan that provides for the collection, transportation, and disposal of certain unwanted prescription drugs." *See* ER 81-88 [Stipulation as to Undisputed

Facts for Cross-Motions for Summary Judgment ("Stipulated Facts") ¶ 1 (cited as "Fact(s) ___")].

The Ordinance is limited to "Covered Drugs" and "Producers." "Covered Drug" means "all drugs as defined in 21 U.S.C. § 321(g)(1) of the Federal Food, Drug and Cosmetic Act," including brand name and generic prescription drugs but not non-prescription drugs. ER 66 (Exhibit A, § 6.53.030.3). "Producer" is defined as an entity or person that fits one of the following categories:

> (i) The Person who manufactures a Covered Drug and who sells, offers for sale, or distributes that [] Covered Drug in Alameda County under that Person's own name or brand.
>
> (ii) If there is no Person who sells, offers for sale, or distributes the Covered Drug in Alameda County under the Person's own name or brand, the producer of the Covered Drug is the owner or licensee of a trademark or brand under which the Covered Drug is sold or distributed in Alameda County, whether or not the trademark is registered.
>
> (iii) If there is no Person who is a producer of the Covered Drug for purposes of paragraphs (i) and (ii), the producer of that Covered Drug is the Person who brings the Covered Drug into Alameda County for sale or distribution.

ER 68 (Exhibit A, § 6.53.030.14). Retailers that merely put their store's label on a Covered Drug and pharmacies that dispense Covered Drugs are not Producers. *Id.*, § 6.53.030.14.

PhRMA's members include approximately one hundred companies that manufacture prescription drugs that are sold, offered for sale, or distributed in Alameda and are therefore "Producers." ER 83 (Fact 11). Twenty-four facilities

(involving twenty-two companies) located in Alameda are licensed to manufacture Covered Drugs for commercial distribution. ER 84 (Fact 14). Three drug manufacturers are headquartered or have their principal places of business in Alameda. ER 84 (Fact 12). Two companies manufacture Covered Drugs in Alameda. ER 84 (Fact 13).

Under the Ordinance, each Producer or group of Producers must participate in an approved plan for a "Product Stewardship Program" to collect and dispose of Covered Drugs that are unused, unwanted, abandoned, or discarded.[1] ER 69-73 (Exhibit A, §§ 6.53.040-.050). A Product Stewardship Program can be operated individually, jointly, or through third-party product stewardship organizations. ER 69 (*id.*, § 6.53.040.A); *see also* ER 82 (Fact 3). Each Producer, group of Producers, and/or organization acting on behalf of a Producer must pay the administrative and operational fees of their Product Stewardship Programs and the administration and enforcement costs incurred by the County. ER 69 (*id.*, § 6.53.040.B). Producers must undertake educational and promotional efforts to enhance the efficacy of their programs. ER 73-74 (*id.*, § 6.53.070).

The Ordinance applies only to a Producer whose Covered Drug is sold, offered for sale, or distributed in Alameda County, thereby ensuring that

[1] The Ordinance provides a process for a Producer to seek an exemption under certain circumstances. ER 141 (Regulations § 5(b)).

manufacturers that do not sell, offer for sale, or distribute Covered Drugs in the County are unaffected by the Ordinance. ER 82-87 (Facts 1, 7, 11, 29 and 33). *See* ER 69 (Exhibit A, § 6.53.040); *see also* ER 83 (Fact 8). Moreover, the Ordinance does not require Producers to do anything in another county or state:

> Nothing in the Ordinance requires that Producers implement stewardship plans in any location or jurisdiction outside of Alameda County. If Producers are required to implement stewardship programs in any other jurisdiction, nothing in the Ordinance requires that the stewardship program implemented in other jurisdictions be the same as the program implemented in Alameda County pursuant to the Ordinance.

ER 83 (Fact 9).

II. Alameda County Has A Substantial Need For The Ordinance.

The Board of Supervisors explicitly recognized the public health and safety hazards caused by unwanted, abandoned, or unused prescription drugs: "The public, particularly children and the elderly, are at significant and unnecessary risk of poisoning due to improper or careless disposal of prescription drugs and the illegal re-sale of prescription drugs. . . ." ER 65 (Exhibit A, § 6.53.010.B). Academic and government research supports Alameda County's concerns. *See, e.g.*, Randall Bond, *et al.*, *The Growing Impact of Pediatric Pharmaceutical Poisoning*, 160 J. Pediatr. 265, 270 (2012) (stating that more than 500,000 children a year under the age of 5 "are exposed to pharmaceuticals in a potential poisoning event," and that pediatric pharmaceutical exposures have risen, likely due to the

increase in the number of medications in the home); Dept. of Health and Human Services, National Center for Health Statistics, *Drug Poisoning Deaths in the United States*, 1980-2008, pp. 1 & 5 (Dec. 2011) (finding, "[i]n 2008, the number of poisoning deaths exceeded the number of motor vehicle traffic deaths and was the leading cause of injury death for the first time since at least 1980" and "[m]isuse or abuse of prescription drugs . . . is responsible for much of the increase in drug poisoning deaths. . . .").

Alameda's Board of Supervisors also recognized the serious environmental problems caused by improper disposal of prescription drugs: "Our groundwater and drinking water are being contaminated by unwanted, leftover or expired prescription drugs passing through our wastewater and treatment centers. . . ." ER 65 (Exhibit A, § 6.53.010.C). Alameda is not alone in identifying the accumulation of pharmaceuticals in waterways. *See, e.g.*, Dept. of Interior, United States Geological Survey, *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance*, p. 1208 (Jan. 2002) (discussing pharmaceuticals in waterways and the problems caused by even low levels of contamination, including "increas[ing] the rate at which pathogenic bacteria develop resistance to" antibiotics); Jeff Donn, *et al.*, *AP: Drugs Found in Drinking Water*, USA Today, Sept. 12, 2008 (quoting the director of environmental technology at Merck & Co.,

Inc.—a member of PhRMA and BIO—as admitting that "[t]here's no doubt about it, pharmaceuticals are being detected in the environment and there is genuine concern that these compounds, in the small concentrations that they're at, could be causing impacts to human health or to aquatic organisms").

Given these serious harmful effects, Alameda's Supervisors determined that "the County of Alameda has a substantial interest in, and a substantial need for, a drug stewardship program." *See* ER 65 (Recitals and Findings at Exhibit A, §§ 6.53.010 *et seq.*). As a result of this determination, the County passed the Ordinance to address the environmental, health, and safety dangers posed by the disposal of prescription drugs. Indeed, PhRMA has stipulated that "the Ordinance's environmental, health and safety benefits are not contested for purpose[s] of the cross-motions for summary judgment." ER 87 (Fact 37).[2]

III. Product Stewardship Programs Are A Recognized Means Of Safely Disposing Of Dangerous Products.

While the Ordinance may be a "first-in-the-nation" ordinance with regard to the disposal of unwanted medications, see Appellants' Brief ("PhRMA Brief") at 25, its underlying theory is not new. Rather, it is an example of "Extended Producer Responsibility" or "EPR." As stated in the California Health and Safety Code: "The EPR framework recognizes that the responsibility for the end-of-life

[2] Because PhRMA has stipulated to these facts, Alameda provides this information on the dangers associated with unwanted prescription drugs for context.

management of discarded products and materials rests primarily with the producers. . . ." Recitals to Cal. Health & Safety Code § 25214.8.10 *et seq.* Requiring that Producers establish a Drug Stewardship Program or utilize the services of a stewardship organization appropriately places responsibility on Producers for the substantial disposal risks embedded in their products when they are manufactured. "In practice, EPR has been implemented through product take-back legislation, which requires manufacturers to take back their products after consumer use or pay a fee to an organization that will collect and recycle the products." *See* Noah Sachs, *Planning the Funeral at the Birth: Extended Producer Responsibility in the European Union and the United States*, 30 Harv. Envtl. L. Rev. 51, 53 (2006).

The Ordinance employs EPR principles by requiring that Producers be responsible for the problematic post-consumer disposal phase of their products and cease shifting the significant costs of disposal onto the County and its residents. The Ordinance is similar to a number of California EPR statutes relating to the disposal of carpet (Cal. Pub. Resources Code §§ 42970 *et seq.*), paint (*id.*, §§ 48700 *et seq.*), mercury thermostats (Cal. Health & Safety Code §§ 25214.8.10 *et seq.*), and pesticide containers (Cal. Food & Agric. Code § 12841.4).

IV. The Ordinance Is A Low Cost Solution To The Problems Caused By Unwanted Household Prescription Drugs.

The costs of the Ordinance to Producers are *de minimis*. According to Alameda County's estimate, the Ordinance's stewardship program, including regulatory oversight, will cost all Producers approximately $530,000 per year. ER 86 (Facts 28 and 30). According to PhRMA's estimate, the Ordinance has start-up costs of $1.1 million and annual costs of $1.2 million. ER 85-86 (Facts 26, 27). While the difference in annual estimated costs is $670,000 (PhRMA's $1.2 million versus Alameda's $530,000), the "parties believe that the difference between their estimates is not material to the outcome" of this case. ER 86 (Fact 30).

The Ordinance provides that costs are to be allocated fairly and proportionately based on each Producer's share of Covered Drug sales in the County. ER 82 (Fact 3). The costs of the Ordinance "would not be paid by any single Producer or financed solely by the approximately 100 members of [PhRMA] that are Producers." ER 86 (Fact 29); ER 71, Exhibit A, § 6.53.050.A.9. Based on Alameda's estimate, the Ordinance would therefore impose an average annual industry-wide cost on each Producer of less than $5,300, and PhRMA's estimate results in an average annual industry-wide cost of less than $12,000.

In 2005, total prescription drug sales in the United States were nearly $250 billion. ER 87 (Fact 32). By 2011, annual prescription drug sales had risen

by almost 30 percent to approximately $320 billion. *Id.* Annual Alameda County retail pharmaceutical sales in 2010 were estimated at $965 million. ER 87 (Fact 34). Thus, using either party's estimate, the annual cost that Producers will incur to comply with the Ordinance is only a tiny fraction of the drug revenues enjoyed by Producers.

While Producers may not charge a specific point of-sale or point-of-disposal fee to recoup their costs, *see* ER 69 (Exhibit A, § 6.53.040.B.3), the Ordinance does not prohibit Producers from recovering the modest costs of their Product Stewardship Program by increasing prices on Covered Drugs sold in Alameda. In the alternative, Producers may use their massive revenues simply to absorb the costs.

V. The Litigation In The District Court.

PhRMA alleged in the Complaint that the Ordinance violates the dormant Commerce Clause. The parties agreed to bring cross-motions for summary judgment based on Stipulated Facts. *See* ER 81-93.

A. PhRMA's Arguments In The District Court.

PhRMA's main argument in the District Court was that the Ordinance *per se* violates the dormant Commerce Clause because it directly regulates interstate commerce in both its purpose and effect, relying on *NCAA v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993). PhRMA also argued that the Ordinance is *per se*

unconstitutional because it discriminates against out-of-County Producers in favor of Alameda taxpayers and consumers and is therefore protectionist. PhRMA relied heavily on the fact that all Covered Drugs cross the Alameda County line before sale, even though some of those drugs are manufactured in the County, some companies have their headquarters or principal places of business in the County, and other companies are licensed to manufacture prescription drugs in the County. PhRMA also asserted that the Ordinance is equivalent to a discriminatory tariff, which is prohibited under the Commerce Clause.

PhRMA also claimed that the Ordinance's undisputed environmental, health, and safety benefits to Alameda County were outweighed by the burden on commerce under the standard set by the Supreme Court in *Pike*.

B. The District Court's Decision And Judgment.

Based on the Stipulated Facts, the District Court rejected PhRMA's arguments and granted Alameda's motion for summary judgment, concluding:

> Because the ordinance does not discriminate against out-of-state actors in favor of local persons or entities, and does not otherwise impermissibly burden interstate commerce . . . defendants' motion [is] granted."

ER 2 (Order at 2).

In reaching this conclusion, Judge Seeborg rejected the argument that *NCAA v. Miller* is applicable because, in that case, the challenged Nevada state law was a direct burden on interstate commerce that required the NCAA to conduct its

own enforcement proceedings in every state in accordance with Nevada law. ER 9 (Order at 9, citing *NCAA*, 10 F.3d at 639). By contrast, "the Ordinance Plaintiffs [PhRMA] challenge here is not specifically directed at regulating interstate organizations and has no remotely similar consequence to any conduct occurring outside county borders." *Id.*

Judge Seeborg specifically found that "the Ordinance here neither purports to regulate interstate commerce nor does so as a practical matter." *Id.* He recognized that

> [n]othing in the structure of the Ordinance targets producers on the basis of their location—they are being required to participate in providing take-back programs because they sell prescription drugs in the county, not because they are out-of-state actors. Nothing in the Ordinance will require, as a practical matter, any producer to alter its manner of doing business in any jurisdiction outside Alameda County. . . .

Id.

Judge Seeborg also rejected the argument that the "discrimination" on which PhRMA relied established a *per se* violation of the Commerce Clause. Rather, he found that such discrimination

> is indisputably not being visited on out-of-state producers as a means of favoring in-state producers. . . . In the absence of 'differential treatment favoring local entities over substantially similar out-of-state interests,' the kind of discrimination potentially prohibited by the dormant commerce clause is not implicated.

ER 8 (Order at 8, citing *Dept. of Revenue of Kentucky v. Davis*, 553 U.S. 328, 343 (2008)). Judge Seeborg further found that "the happenstance that most producers of prescription drugs are located outside Alameda County is insufficient to transform what is fundamentally a local measure into one that could be found to burden interstate commerce impermissibly." ER 10 (Order at 10 (citations omitted)).

Judge Seeborg further found that the Ordinance is not a tariff, which "taxes goods imported from other States, but does not tax similar products produced in State." ER 10 (Order at 10, quoting *West Lynn Creamery v. Healy*, 512 U.S. 186, 193 (1994)). Finally, noting that PhRMA did not question "that the interests Alameda County had in enacting the ordinance were legitimate," Judge Seeborg rejected the contention "that those interests could be equally well served through take-back programs funded in another manner." *Id.* Instead, he concluded as follows:

> Arguing that an alternative regime would have *no* burden on interstate commerce does not establish that the minimal burden this Ordinance arguably imposes on interstate commerce "clearly exceeds the local benefits." Defendants have adequately shown that the Ordinance serves a legitimate public health and safety interest, and that the relatively modest compliance costs producers will incur should they choose to sell their products in the county do not unduly burden interstate commerce.

Id. Judgment in Alameda County's favor was entered accordingly.

SUMMARY OF ARGUMENT

PhRMA asks this Court to substitute its judgment for the judgment of the duly elected Board of Supervisors in enacting the Ordinance. The Supreme Court and the Ninth Circuit, however, have repeatedly recognized that the dormant Commerce Clause is not to be used to second guess legislative decisions. Moreover, special deference is accorded to local health and safety regulations and local governmental discretion over waste management. Alameda's Ordinance is such a regulation and complies with United States Supreme Court and Ninth Circuit precedents interpreting and applying the dormant Commerce Clause.

PhRMA's arguments on appeal can be broadly classified into two categories: (1) arguments premised on matters that are irrelevant to the dormant Commerce Clause, and (2) arguments premised on facts that are not in the record. A correct dormant Commerce Clause analysis establishes that there is no *per se* violation, and that, under the *Pike* test, PhRMA cannot meet its burden to prove that the incidental burden on interstate commerce are clearly excessive in relation to the Ordinance's undisputed health, safety and environmental benefits to Alameda County's residents.

I. PhRMA Relies On Irrelevant Contentions.

Perhaps PhRMA's most glaring legally irrelevant contention is that the Ordinance is unconstitutional because Producers cannot recoup their costs (i.e.,

avoid any burden). But the dormant Commerce Clause is not concerned with the profits of regulated companies or their ability to recoup the regulatory costs incurred in complying with such regulations. Furthermore, the Ordinance does not prohibit Producers from raising prices on Covered Drugs sold in Alameda County in order to recoup costs, and there is no evidence that they cannot do so. Contrary to PhRMA's claim, the Ordinance does not require prices to be raised to any consumers anywhere.

PhRMA's other legally irrelevant contentions are that the Ordinance shifts costs from the County to Producers, that most (but not all) Producers are located outside the County, that all Covered Drugs cross the County line, and that the Ordinance will require Producers to enter into a new business of waste disposal. Nothing in dormant Commerce Clause jurisprudence compels, or even suggests, the conclusion that any of these contentions is a basis on which a court could find the Ordinance to be unconstitutional.

II. PhRMA Relies On Arguments Unsupported By Any Evidence Or That Are Contrary To The Undisputed Facts.

The facts in evidence do not support PhRMA's legal arguments. PhRMA's claim that there is discrimination against out-of-County producers fails because the Ordinance applies equally and evenhandedly to all Producers, regardless of location. ER 82-83 (Facts 4-6). PhRMA fails to provide any evidence of discrimination between substantially similar competitors, which is required to find

the Ordinance unconstitutional. Instead, PhRMA argues that Producers are substantially similar to Alameda County and its residents, and also that Producers are substantially similar to the local pharmacies that are customers that purchase Producers' products. But "substantial similarity" between plaintiffs' members and the County's residents, or pharmacies does not exist within the meaning of well-settled Commerce Clause jurisprudence because "similarity" relates only to the need for a level playing field for all competitors regardless of their location.

PhRMA claims that the Ordinance functions like a tariff, but there is no evidence that the Ordinance burdens Covered Drugs manufactured out of the County more than Covered Drugs manufactured in the County. Similarly, there is no evidence to support PhRMA's argument that the Ordinance is protectionist. Indeed, the contrary is undisputed. ER 82-83 (Facts 4-6).

There is also no evidence to support PhRMA's claim of Balkanization, and there is no reason to expect commercial retaliation from states or other counties against Alameda County. The Ordinance does not require any state or other county to do anything, creates no barrier to the flow of commerce, and provides no commercial advantage for local competitors. The possibility that different jurisdictions may adopt similar or different drug stewardship programs as one aspect of their local governmental responsibility for waste disposal will not Balkanize commerce. The *Pike* test for comparing the burden on commerce to the

local benefit will determine whether counties or states can establish EPR programs for Covered Drugs or any other products.

Contrary to the evidence, PhRMA claims that out-of-County Producers have no involvement in the County. However, PhRMA has stipulated to the facts that out-of-County manufacturers subject to the Ordinance market, sell, offer for sale, or distribute Covered Drugs in the County. ER 82-87 (Facts 1, 7, 8, 11, 29 and 33). Furthermore, PhRMA ignores the evidence that three of its members have their headquarters or principal places of business in Alameda, two of its members manufacture Covered Drugs in Alameda ER 84 (Facts 12-13), and twenty-four drug manufacturing facilities (for twenty-two companies) are licensed in the County to manufacture prescription drugs for commercial distribution. ER 84 and 95 (Fact 14 and Exhibit B). PhRMA also ignores the substantial print and television advertising for pharmaceutical products directed at Alameda County residents. The fact that Producers located in Alameda send their products out-of-County for packaging or other reasons and then return them to the County for sale is irrelevant and does not insulate the pharmaceutical industry from all regulation.

Similarly unsupported by the evidence is PhRMA's contention that the Ordinance has an impermissible extraterritorial effect. In fact, the evidence in the record demonstrates that the Ordinance does not apply to any manufacturer whose prescription drugs are not sold, offered for sale, or distributed in the County, and

nothing in the Ordinance requires any action by any Producer for sales outside of Alameda County. ER 83 (Facts 8 and 9). Moreover, there is no evidence that the Ordinance dictates where, how, whether, or when Covered Drugs may be manufactured, packaged, marketed, wholesaled, or sold.

PhRMA's final assertion—that Alameda County already performs all of the functions required by the Ordinance—is also without any support in the record. PhRMA asks this Court to nullify Alameda's Supervisors' legislative solution to the dangers to its environment and the health and safety of its residents by speculating that the County is already doing everything provided by the Ordinance and can do a better job than the manufacturers of the products. But the Supreme Court has admonished the judiciary not to substitute its judgment for that of elected legislators, and there is no controlling law that would render the Ordinance a violation of the Commerce Clause based on PhRMA's claim that the County can do a better job by itself. The dormant Commerce Clause only requires courts to evaluate alternatives to a disputed regulation if, unlike the Ordinance, a regulation is a *per se* burden on interstate commerce.

PhRMA does not dispute the essential facts that establish that the Ordinance is constitutional. PhRMA has stipulated to the low cost of the Ordinance to Producers, ER 85-86 (Facts 25, 27 and 30), and to the important health, safety, and environmental benefits for the County. ER 87 (Fact 37). The Ordinance is a

constitutional exercise of Alameda County's police powers, and whether Alameda could bear the full burden alone is irrelevant to its constitutionality.

ARGUMENT

I. The Commerce Clause.

The Commerce Clause of the United States Constitution authorizes Congress to "regulate commerce . . . among the several States. . . ." U.S. Const., Art. 1, § 8, cl. 3. However, its "terms do not expressly restrain 'the several States' in any way. . . ." *Kentucky*, 553 U.S. at 337. Nevertheless, "the Clause has long been understood to have a 'negative' [or 'dormant'] aspect that denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce." *Or. Waste Sys. v. Dep't of Envtl. Quality*, 511 U.S. 93, 98 (1994). As the Supreme Court explained in *Kentucky*:

> The modern law of what has come to be called the dormant *Commerce Clause* is driven by concern about "economic protectionism—that is, regulatory measures designed to benefit in state economic interests by burdening out of state competitors."

553 U.S. at 337 338, *quoting New Energy Co. v. Limbach*, 486 U.S. 269, 273 74 (1988).

State and local governments are empowered to provide legislative solutions to matters of local concern. As the Court recognized in *Kentucky*, 553 U.S. at 338, "The law [relating to the Commerce Clause] has had to respect a cross purpose as well, for the Framers' distrust of economic Balkanization was limited by their

federalism favoring a degree of local autonomy." Thus, "[t]he limitation imposed by the Commerce Clause on state regulatory power is by no means absolute, and the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Maine v. Taylor*, 477 U.S. 131, 138 (1986) (internal quotations omitted).

The Commerce Clause does not preclude, or interfere with, state and local government's "broad regulatory authority to protect the health and safety of [their] citizens and the integrity of [their] natural resources." *Maine*, 477 U.S. at 151. Thus, the Commerce Clause "does not elevate free trade above all other values." *United Haulers Ass'n. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 344 (2007), quoting *Maine*, 477 U.S. at 151. As this Court observed in *Nat'l Ass'n of Optometrists & Opticians v. Harris* ("*Optometrists & Opticians*"), 682 F.3d 1144, 1148 (9th Cir. 2012):

> [T]he Supreme Court has recognized that "under our constitutional scheme the States retain broad power to legislate protection for their citizens in matters of local concern such as public health" and has held that "not every exercise of local power is invalid merely because it affects in some way the flow of commerce between the States. *Great Atl. & Pac. Tea Co. v. Cottrell*, 424 U.S. 366, 371, 96 S. Ct. 923, 47 L. Ed. 2d 55 (1976) (internal quotations and citations omitted).

The Ordinance challenged by PhRMA does not impede the flow of commerce or otherwise violate the Commerce Clause. PhRMA's convoluted arguments that the Ordinance "is not an exercise of [Alameda County's] police

power" and that Alameda is "transferring its traditional police power responsibility . . . to interstate actors" are unsupported by any evidence and are contrary to the Stipulated Facts that provided the basis for the cross-motions for summary judgment in the District Court. Nor does the Ordinance directly burden or regulate interstate commerce, constitute a tariff, or discriminate in favor of local competitors. Even if the Ordinance incidentally burdens interstate commerce, that *de minimis* burden is far outweighed by the stipulated health, safety and environmental benefits it provides.

A. PhRMA Has A High Burden Of Proof To Establish A Violation Of The Dormant Commerce Clause.

In determining whether a local regulation violates the Commerce Clause, the courts traditionally follow a two-tiered approach:

> [1] When a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, we have generally struck down the statute without further inquiry. [2] When, however, a statute has only indirect effects on interstate commerce and regulates evenhandedly, we have examined whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.

S.D. Myers, Inc. v. City & County of San Francisco, 253 F.3d 461, 466 (9th Cir. 2001), quoting *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986). A law is a "direct burden" if its "primary purpose" is to

regulate interstate commerce. *Kleenwell Biohazard Waste & Gen. Ecology Consultants v. Nelson*, 48 F.3d 391, 395 (9th Cir. 1995).

A plaintiff making a facial challenge to a local ordinance must "meet a high burden of proof . . ." and "must 'establish that no set of circumstances exists under which the [Ordinance] would be valid. The fact that [the Ordinance] might operate unconstitutionally under some conceivable set of circumstances is insufficient to render it wholly invalid.'" *S.D. Myers*, 253 F.3d at 467, quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987). *See also Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979) ("The burden to show discrimination rests on the party challenging the validity of the statute. . . ."). PhRMA has not met its "high burden."

These and other controlling Supreme Court and Ninth Circuit precedents establish that the Ordinance does not directly burden, regulate, or discriminate against interstate commerce, is not, and does not act, like a tariff, and is a constitutional exercise of the County's police power. Because this case involves only an incidental burden, the Court does not consider alternatives to the Ordinance. *See Optometrists & Opticians*, 682 F.3d at 1157 ("[A]n examination of alternatives [is required] for discriminatory laws but not for other laws. . . . This distinction is consistent with case law requiring the consideration of restrictive alternatives only when heightened scrutiny is required.").

B. The Supreme Court Has Admonished Courts To Exercise Judicial Restraint In Evaluating The Constitutionality Of Local Laws Related To Health And Safety.

The Supreme Court and the Ninth Circuit have repeatedly reiterated that it is not the role of courts to second guess legislative bodies' solutions to legitimate local issues. *See Kentucky*, 553 U.S. at 341 ("[A] government function is not susceptible to standard dormant *Commerce Clause* scrutiny owing to its likely motivation by legitimate objectives. . . ."). Moreover, a local governmental agency's "power to regulate commerce is at its zenith in areas traditionally of local concern" and "regulations that touch on safety are those that the Court has been most reluctant to invalidate." *Kleenwell*, 48 F.3d at 398.

In *United Haulers*, 550 U.S. at 342-43, Chief Justice Roberts cautioned against interfering with local government decisions regarding waste management: "We should be particularly hesitant to interfere with the Counties' efforts under the guise of the Commerce Clause because '[w]aste disposal is both typically and traditionally a local government function'." The Chief Justice rejected the invitation "to rigorously scrutinize economic legislation passed under the auspices of the police power." *Id.* at 347. *See also Optometrists & Opticians*, 682 F.3d at 1156 ("In most dormant *Commerce Clause* cases, it is not the role of the courts to determine the best legislative solution to a problem."). Admonishing against judicial interference with local governmental decisions, Chief Justice Roberts

concluded: "There was a time when this Court presumed to make such binding judgments for society, under the guise of interpreting the *Due Process Clause*. [Citation omitted.] We should not seek to reclaim that ground for judicial supremacy under the banner of the dormant *Commerce Clause*." *United Haulers*, 550 U.S. at 347.

Justice Brennan expressed a similar conclusion when he wrote in his concurring opinion in *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 680-681 (1981), that "[i]t is not the function of the court to decide whether *in fact* the regulation promotes its intended purpose, so long as an examination of the evidence before or available to the lawmaker indicates that the regulation is not wholly irrational in light of its purposes."

II. The Ordinance Is A Proper Exercise Of Alameda County's Traditional Local Government Function.

Local governments have broad regulatory authority, particularly in the area of waste disposal. "For ninety years, it has been settled law that garbage collection and disposal is a core function of local government in the United States." *USA Recycling v. Town of Babylon*, 66 F.3d 1272, 1275 (2d Cir. 1995). "Congress itself has recognized local government's vital role in waste management, making clear that 'collection and disposal of solid wastes should continue to be primarily the function of State, regional, and local agencies.'" *United Haulers*, 550 U.S. at 344,

quoting Resource Conservation and Recovery Act of 1976, 90 Stat. 2797, 42 U.S.C. § 6901(a)(4).

The Ordinance is designed to regulate the collection and disposal of unwanted Covered Drugs. *See* ER 70 (Exhibit A, § 6.53.050); *see also* ER 82 (Fact 3). The clear and stated purpose of the Ordinance is to protect the health and safety of Alameda's residents and the County's environment. ER 65 (Exhibit A, § 6.53.010.B&C). Though it repeatedly suggests the contrary in its Brief, PhRMA specifically stipulated that "the Ordinance's environmental, health and safety benefits are not contested for purpose[s] of the cross-motions for summary judgment." ER 87 (Fact 37.)

Given the purpose and effect of the Ordinance, it falls squarely within Alameda's broad regulatory authority and is entitled to substantial deference in evaluating its constitutionality. *See United Haulers*, 550 U.S. at 344. As the Supreme Court observed in *Huron Portland Cement Co. v. Detroit*:

> In determining whether the [County] has imposed an undue burden on interstate commerce, it must be borne in mind that the Constitution when "conferring upon Congress the regulation of commerce, it was never intended to cut the States off from legislating on all subjects relating to the health, life, and safety of their citizens, though the legislation might indirectly affect the commerce of the country. Legislation, in a great variety of ways, may affect commerce and persons engaged in it without constituting a regulation of it within the meaning of the Constitution."

362 U.S. 440, 443 (1960), quoting *Sherlock v. Alling*, 93 U.S. 99, 103 (1876). *See also H. P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 535 (1949) (recognizing that the Supreme Court generally has supported the rights of states to "impose even burdensome regulations in the interest of local health and safety"). As this Court said in *Kleenwell*, 48 F.3d 391 (9th Cir. 1995),

> [R]egulations that touch upon safety . . . are those that "the Court has been most reluctant to invalidate." Indeed, "if safety justifications are not illusory, the Court will not second-guess legislative judgment about their importance in comparison with related burdens on interstate commerce." Those who would challenge such bona fide safety regulations must overcome "a strong presumption of validity."

48 F.3d 391, 401 n.11 (9th Cir. 1995) quoting *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 670 (1981).

Throughout its Brief, PhRMA argues that, despite Alameda's broad regulatory authority relating to waste disposal, the County can only exercise that power by directly operating a drug waste disposal program by itself. *See, e.g.*, PhRMA Brief at 24-25. PhRMA, however, fails to cite any authority that the County's power is so limited. Rather, as recognized by the Second Circuit in *USA Recycling*, local governments have a variety of methods available for regulating waste disposal, including directly operating a program, operating a program through an independent contract, or "rely[ing] on a closely regulated private market." *USA Recycling*, 66 F.3d at 1275.

Here, Alameda County has chosen to address the growing concern over the disposal of unwanted Covered Drugs that harm its residents and environment by regulating the private market occupied by Producers and requiring that Producers take responsibility for the disposal of the Covered Drugs they sell, offer for sale, or distribute within the County. *See* ER 65-80 (Ordinance), ER 81-88 (Facts 1-38). Given Alameda's broad regulatory authority concerning this traditionally and typically local government function, it was well within its power to enact the Ordinance. As discussed below, PhRMA's scattershot arguments fail to provide any compelling reason why the Ordinance is not a valid exercise of Alameda County's right and obligation to protect the health and safety of its residents and its environment.

III. The Ordinance's Purpose Is To Protect The Health And Safety Of Alameda Residents And The Environment.

The stated purpose of the Ordinance is to address "the County of Alameda['s] substantial interest in, and [] substantial need for, a drug stewardship program" for "the health and welfare of the residents of the County of Alameda, particularly children and the elderly, [which] would be improved and advanced by the proper disposal of unwanted, expired or unneeded prescription drugs. . . ." ER 65 (Recitals to Exhibit A). To accomplish this purpose, Alameda implemented an EPR program allocating the Ordinance's responsibilities to in-County and out-of-County Producers alike, not simply out-of-County Producers, as PhRMA

argues. The EPR disposal program requires Producers to take responsibility for dealing with disposal of their products, which the pharmaceutical companies have failed to do. Thus, both the Ordinance's central purpose (to address an area of traditional governance and legitimate local concern) and the Ordinance's method (to require that all Producers, regardless of location, take responsibility for disposal of Covered Drugs) are consistent with the legislative judgment made by the Board of Supervisors, and neither directly burdens nor regulates interstate commerce.

While denying the stipulated health, safety and environmental benefits of the Ordinance,[3] PhRMA argues that the Ordinance's "real" purpose is to burden interstate commerce by shifting the cost of disposal to out-of-County entities (PhRMA Brief at 25), even though pharmaceutical companies have a substantial presence in the County. ER 84 (Facts 12, 13 and 14).

PhRMA simply does not agree with the purpose of, and the need for, the Ordinance. Rather, it "believe[s] that in-home disposal, where unwanted pharmaceutical products are discarded with the household trash, is an environmentally preferable way to dispose of unwanted medicines." PhRMA Brief at 2, n.1. But the elected legislators of Alameda County disagree with the opinions

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[3] PhRMA blatantly asserts that "the Ordinance cannot serve any environmental or other police power purpose," (PhRMA Brief at 25) notwithstanding the undisputed facts—and judgment of the Board of Supervisors—that the Ordinance is a necessary means of protecting the environment and the health and safety of its residents. ER 65, 87 (Fact 37).

of the three plaintiff pharmaceutical trade associations that disposal of unused prescription drugs in household trash is environmentally safe or without risks to health and safety. Moreover, PhRMA has agreed and stipulated that the Ordinance—which will take prescription drugs out of household trash—provides health, safety and environmental benefits to Alameda residents. ER 87 (Fact 37).

PhRMA disingenuously asserts that "[t]he Ordinance did not *establish* a drug collection program" because Alameda County "already had one (which still continues)." PhRMA Brief at 24. While Alameda of course performs many waste disposal functions, there is no evidence that the County already performs all of the functions of the Ordinance. More importantly, whether the County had some program prior to the Ordinance is not relevant to a Commerce Clause analysis. *See Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 809 (1976) ("[T]his chronology [of Maryland's previous program] does not distinguish the case, for Commerce Clause purposes, from one in which a State offered bounties only to domestic processors from the start.").

IV. The Ordinance Does Not Discriminate Against Interstate Commerce Or Impermissibly Favor Local Interests.

PhRMA argues that the Ordinance is unconstitutional because it expressly favors local interests—namely, local taxpayers, businesses and pharmaceutical consumers. *See e.g.*, PhRMA Brief at 32-33. PhRMA asserts that the threshold test for legitimacy of the Ordinance is whether the exercise of Alameda's "police

power law treats local companies better than out-of-state companies." *Id.* at 22. PhRMA's local favoritism argument is wrong because it is undisputed that the Ordinance treats substantially similar local and out-of-state companies exactly the same. ER 82 (Fact 4). *See Raymond Motor Transportation, Inc. v. Rice*, 434 U.S. 429, 440 (1978) ("[I]t never has been doubted that much state legislation, designed to serve legitimate state interests and applied without discrimination against interstate commerce, does not violate the *Commerce Clause* even though it affects commerce.").

A. The Dormant Commerce Clause Defines Discrimination As Favoring Local Competitors Over Out-Of-State Competitors, Not As Favoring Public Entities, Local Consumers, Taxpayers Or Non-Competing Businesses Over Competing Businesses.

It is well established that "any notion of discrimination assumes *a comparison of substantially similar entities.*" *See Kentucky*, 553 U.S. at 342, quoting *United Haulers*, 550 U.S. at 342 (emphasis added); *see also General Motors Corp. v. Tracy*, 519 U.S. 278, 298 (1997). Entities are substantially similar when there exists "actual or prospective *competition* between the supposedly favored and disfavored entities in a single market." *General Motors*, 519 U.S. at 300 (emphasis added). As the Supreme Court concluded in *General Motors*:

> [I]n the absence of actual or prospective competition between the supposedly favored and disfavored entities in a single market there can be no local preference, whether by express discrimination against interstate commerce or undue burden upon it, to which the dormant *Commerce Clause* may apply.

Id.

The Ordinance treats substantially similar entities exactly the same. All competing Producers, regardless of location, are required to take responsibility for disposal of unwanted Covered Drugs through participation in an approved Product Stewardship Program or other approved plan, and Covered Drugs, regardless of origin, are the subject of the Ordinance. *See* ER 68 (Exhibit A, § 6.53.030.14, defining "Producer" without reference to location) and ER 66 (Exhibit A, § 6.53.030.3, defining "Covered Drug" without reference to the Producer's location). While the parties expressly stipulated that "[t]he Ordinance, on its face, does not impose different requirements on Producers within Alameda County and Producers outside of Alameda County" (ER 82 (Fact 4)), PhRMA's Brief repeatedly argues to the contrary.

Ignoring the undisputed equal treatment of all Producers, PhRMA contends that the Ordinance impermissibly favors "local interests" because it benefits Alameda County, local taxpayers, consumers, and retail businesses. *See, e.g.*, PhRMA Brief at 40-43. These "local interests," however, are not substantially similar to Producers because Alameda County local taxpayers, consumers, and retail businesses do not compete with Producers in any market.

The County and Producers are not substantially similar for purposes of the Commerce Clause. The Supreme Court expressly stated in *Kentucky* that "[t]here

is no forbidden discrimination because Kentucky, as a public entity, does not have to treat itself as being 'substantially similar' to the other bond issuers in the market." 553 U.S. at 343. As Chief Justice Roberts noted in *United Haulers*: "Our opinion simply recognizes that a law favoring a public entity and treating all private entities the same does not discriminate against interstate commerce as does a law favoring local business above all others." 550 U.S. at 345 n.6.

Justice Scalia similarly explained in his concurring opinion in *United Haulers* that "[n]one of this Court's cases concludes that public entities and private entities are similarly situated for *Commerce Clause* purposes. To hold that they are 'would broaden the negative Commerce Clause beyond its existing scope, and intrude on a regulatory sphere traditionally occupied by . . . the State.'" 550 U.S. at 348. He also correctly observed that the "law at issue [in *United Haulers*]… benefits a *public entity* performing a traditional local-governmental function and treats *all private entities* precisely the same way." *Id*. at 348. The same is true here.

The local businesses exempted from the definition of "Producer"—*i.e.*, retailers that put their store's label on a Covered Drug and pharmacists that only dispense Covered Drugs—are customers, not competitors, of multiple Producers. Thus, retail businesses, on the one hand, and Producers, on the other hand, are not substantially similar entities that compete against each other "in a single market."

Furthermore, local taxpayers and consumers do not compete with Producers in any market whatsoever. *See General Motors*, 519 U.S. at 299-300; *see also Pharmaceutical Research & Mfrs. of America v. Walsh*, 538 U.S. 644, 670 (2003) ("*Pharma. v. Walsh*") (noting that "the [rebate] payments to the local pharmacists provide no special benefit to competitors of rebate paying manufacturers.").

PhRMA's attempts to circumvent the undisputed fact that the Ordinance is nondiscriminatory by engaging in an "apples and oranges" comparison of Producers versus Alameda County, local taxpayers, consumers and retailers should be rejected. Rather, the Commerce Clause is intended to ensure a level playing field for local and non-local competitors. *See Houlton Citizens' Coalition v. Town of Houlton*, 175 F.3d 178, 188 (1st Cir. 1999) ("[T]o the extent that in-state and out-of-state bidders are allowed to compete freely on a level playing field, there is no cause for constitutional concern."). Here, because all competitors are treated exactly the same under the Ordinance, the competitive playing field remains level, and "there is no cause for constitutional concern." *See id*.

B. The Location Of Most Producers Outside Of Alameda County Does Not Make The Ordinance Discriminatory.

PhRMA argues that the Ordinance is unconstitutional because most or all Producers are located out-of-County. *See, e.g.*, PhRMA Brief at 33. This argument has been rejected by the Supreme Court on multiple occasions and glosses over the fact that several Producers are located in Alameda and that

approximately $3 billion of Covered Drugs are actually manufactured in the County. ER 84 (Facts 12-14 and 17). Even if there were no drug manufacturers located in Alameda County, the Ordinance would still be constitutional.

Exxon Corp. v. Governor of Maryland, 437 U.S. 117 (1978), is a leading case on the right of state and local governments to regulate the conduct of out-of-state producers. In *Exxon*, a Maryland statute provided that "a producer or refiner of petroleum products (1) may not operate any retail service station within the State, and (2) must extend all 'voluntary allowances' uniformly to all service stations it supplies" in Maryland. *Id.* at 119-120. "However, no petroleum products [were] produced or refined in Maryland, and the number of stations actually operated by a refiner or an affiliate [was] relatively small, representing about 5% of the total number of Maryland retailers." *Id.* at 123. As a result, the law's effect fell "solely on interstate companies." *Id*. at 125.

Exxon and several other refiners challenged the law as discriminatory because its burden fell solely on interstate companies. *Id.* at 121-22, 125. The Supreme Court expressly rejected that argument, which is the same argument asserted by PhRMA here: "This fact does not lead, either logically or as a practical matter, to a conclusion that the State is discriminating against interstate commerce at the retail level" and "*[t]he fact that the burden of a state regulation falls on*

some interstate companies does not, by itself, establish a claim of discrimination against interstate commerce." *Id.* at 125, 126 (emphasis added).

The Supreme Court confirmed the reasoning of *Exxon* in *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69 (1987). In *CTS*, Indiana enacted a law restricting the acquisition of control shares of Indiana corporations. *Id.* at 73-74. The plaintiff unsuccessfully argued that it was discriminatory because, "as a practical matter, most hostile tender offers are launched by offerors outside Indiana." *Id.* at 88. Relying on *Exxon*, the *CTS* Court held that a law does not violate the Commerce Clause simply "because it [applies] most often to out of-state entities." *Id.* Indeed, notwithstanding the fact that the law largely affected out-of-state offerors, the Court held that, "[b]ecause nothing in the Indiana Act imposes a greater burden on out-of-state offerors than it does on similarly situated Indiana offerors, we reject the contention that the Act discriminates against interstate commerce." *Id.*

In *Pharma. v. Walsh*, 538 U.S. 644, 656 (2003), PhRMA argued, as it does here, that substantially all manufacturers were located outside of Maine and therefore could not be required to pay rebates in Maine on their drugs sold by Maine pharmacies. Even though substantially *all* affected manufacturers were out-of-state, the Supreme Court rejected the argument that Maine's drug rebate statute "constitutes impermissible extraterritorial regulation, and . . . discriminates

against interstate commerce in order to subsidize in-state retail sales. . . ." *Id.* at 669. The Supreme Court recognized that the dispositive discrimination test was not whether competitors were located outside the state, but whether a competitor could gain any economic advantage by being located in the state. "A manufacturer could not avoid its rebate obligation by opening production facilities in Maine and would receive no benefit from the rebates even if it did so; the payments to the local pharmacists provide no special benefit to competitors of rebate-paying manufacturers." *Id.* at 670.

In each of those cases, there were no in-state competitors, and the Supreme Court held that there was no discrimination against out-of-state competitors. *Exxon*, *CTS*, and *Pharma. v. Walsh* dispose of PhRMA's argument here as each held that a local statute that applies only to competitors outside of the locality does not, in and of itself, render a law discriminatory for Commerce Clause purposes. *See CTS*, 481 U.S. at 88; *Exxon*, 437 U.S. at 125-26. Thus, the fact that most Covered Drugs sold in Alameda come from companies based outside of the County does not make the Ordinance discriminatory. Rather, to establish discrimination, PhRMA must show disparate treatment between similarly situated entities, which it has not shown. *See Exxon Corp.*, 437 U.S. 126: "If the effect of a state regulation is to cause local goods to constitute a larger share, and goods with an out-of-state source to constitute a smaller share, of the total sales in the

market . . . the regulation may have a discriminatory effect on interstate commerce." *Id*. at 126, n.16. PhRMA has not made, and cannot make, such a showing.

V. The Ordinance Is Not A Tariff.

The Ordinance does not have the purpose or effect of a tariff as PhRMA claims. PhRMA Brief at 29-33. The District Court's Order explained that the Ordinance is not a tariff because a tariff "taxes goods imported from other states, but does not tax similar products produced in state," which is the defining characteristic of a tariff. ER 10 (Order at 10). *See West Lynn Creamery v. Healy*, 512 U.S. 186, 193 (1994) (emphasis added). *See also Kentucky*, 553 U.S. at 367; *Camps Newfound/Owatonna v. Town of Harrison*, 520 U.S. 564, 575 (1997).

In-County and out-of-County Producers have identical responsibilities for a Product Stewardship Program. Any burdens the Ordinance places on Producers of Covered Drugs coming into the County are identical to burdens placed on Producers of Covered Drugs originating in the County. Thus, the District Court correctly concluded that the Ordinance "shares none of these salient features" of a tariff. ER 10 (Order at 10:2-7).

VI. The Ordinance Is An Incidental Burden On Interstate Commerce.

Any regulation of business conducted in a county or state is a burden of some sort. If that business is conducted by an entity that is located outside of the

county or state, the regulation can always be superficially characterized as a burden on interstate commerce. However, the fact that the burden of a regulation falls on one or more non-local entities does not mean that the regulation "directly burdens" or "directly regulates" interstate commerce.

"The Supreme Court has distinguished between two types of state regulations burdening interstate commerce: (1) those that directly burden interstate commerce . . . and (2) those that burden interstate transactions only incidentally." *Kleenwell*, 48 F.3d at 395. Laws that are a direct burden "are generally struck down unless the state can demonstrate that a legitimate local interest is served by the regulation and no less discriminatory alternative exists. . . ." *Id.* In determining whether a law is a "direct burden" or an "incidental burden" on interstate commerce, courts "must consider the purpose of the . . . regulation as well as its effects." *Id.* at 398.

Because the primary purpose and effect of the Ordinance is to address health, safety, and environmental issues that have been held as a matter of law to be legitimate local concerns, the Ordinance is an incidental, rather than direct, burden on interstate commerce. *See Kleenwell*, 48 F.3d at 397 (holding that law was an incidental burden because its primary purpose was to protect the safety of residents by regulating solid medical waste disposal).

A. The Ordinance Does Not Require Any Out-of-County Conduct.

The Ordinance does not regulate sales or conduct outside the County. Producers are not required to do anything and are not prohibited or hindered from taking any action, outside the County. "Nothing in the Ordinance requires that Producers implement stewardship plans in any location or jurisdiction outside of Alameda County." ER 83 (Fact 9). Nor does the Ordinance regulate any manufacturer whose Covered Drugs are not sold in Alameda County. ER 83 (Fact 8).

Even if the Ordinance did require out-of-County conduct by Producers, it would still be constitutional. In *National Electrical Manufacturers Ass'n v. Sorrell*, 272 F.3d 104, 107 (2d Cir. 2001), a unanimous dormant Commerce Clause opinion written by the Chief Judge and joined by now Supreme Court Justice Sotomayor, the Second Circuit upheld a Vermont regulation requiring manufacturers "of some mercury-containing products to label their products and packaging to inform consumers that the products contain mercury and, on disposal, should be recycled or disposed of as hazardous waste." *Id.* The Court acknowledged that the packaging regulation required "out-of-state commerce to be conducted at the regulating state's discretion" and might cause manufacturers to have to "modify their production and distribution systems. . . ." *Id.* at 110. The court noted:

> To the extent the statute may be said to "require" labels on lamps sold outside Vermont, then, it is only because the manufacturers are unwilling to modify their production and distribution systems to differentiate between Vermont-bound and non-Vermont bound lamps.

Id. The regulation was permissible because "manufacturers are not required to adhere to the Vermont [regulation] in other states." *Id.* at 111.

In *Ass'n. Des Eleveurs De Canards Et D'oies Du Quebec*, 729 F.3d 937, 948 (9th Cir. 2013) ("*Canards*"), out-of-state producers of foie gras challenged a California regulation banning the sale of foie gras under certain circumstances. This Court upheld the California Health and Safety Code regulation banning the sale by any in-state or out-of-state entity "that is the result of force feeding a bird regardless of the product's source or origin." Cal. Health & Safety Code § 25982. Because the ban applied to the sale of both "intrastate and interstate products," it was not discriminatory and did not impose a substantial burden on interstate commerce notwithstanding plaintiffs' claimed loss of $5 million in sales. *Canards*, 729 F.3d at 952.

PhRMA's incorrect reading of the dormant Commerce Clause would render unconstitutional many important and well-established California laws that require out-of-State manufacturers to take actions outside California that are necessary to protect the health, safety, and environment of California residents. For example, California has certain composition, recyclability, and reusability requirements for "rigid plastic packaging containers" sold in California by direct sales, retail sales,

and remote sales through distributors, wholesalers, and the internet. *See* California Code of Regulations Section 17944. Products with toxic or cancer causing materials manufactured out-of-state (and in-state) must bear Proposition 65 warnings if sold in California, regardless of how the product enters California. *See* California Health and Safety Code Sections 25249.5-25249.13. Certain animals raised out-of-state must be tested out-of-state for certain diseases before being allowed in California. *See* California Code of Regulations sections 758(b), 753.1(e), 796.4(b)(4), 796.5 and 820.3.

All of these laws or regulations are intended to protect the health, safety and environment of California residents, and none has been found to violate the Commerce Clause.

B. The Out-Of-County Location Of Most Producers Does Not Result In An Impermissible Direct Burden On Interstate Commerce.

PhRMA claims that the Ordinance is a "direct burden" on interstate commerce because most drugs used in Alameda arrive from outside the County. PhRMA Brief at 33, 47-52; ER 84 (Facts 12, 13 and 14). PhRMA unsuccessfully made the same "direct burden" argument before the Supreme Court in *Pharma. v. Walsh*.

As described above, the Supreme Court in *Pharma. v. Walsh* upheld a Maine law requiring rebates to be paid by pharmaceutical manufacturers to Maine pharmacies that reduced Maine's costs for Medicaid. The Court expressly

concluded that the law was not a direct burden on interstate commerce. As in this case, PhRMA argued that almost all sales by manufacturers of prescription drugs were made out of state due to the "Companies methods of distribution." *Id*. Thus, PhRMA claimed, the Maine drug rebate program benefiting low income residents "constituted impermissible extraterritorial regulation. . . ." *Id*. at 669. PhRMA submitted four affidavits to "describe the nature of the association and the companies' methods of distribution, emphasizing the fact that, with the exception of sales to two resident distributors, all of their prescription drug sales occur outside of Maine." *Id*. at 656. The Supreme Court rejected these arguments, concluding:

> [T]he Maine Act does not regulate the price of any out of state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price. Similarly, Maine is not tying the price of its in state products to out of state prices . . . the rule that was applied in *Baldwin* and *Healy* accordingly is not applicable to this case.

Id. at 669 (citation omitted).

As it did in *Pharma. v. Walsh*, PhRMA relies here on *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), and *Healy v. Beer Institute, Inc.*, 491 U.S. 324 (1989). PhRMA Brief at 49. In those cases, the Supreme Court struck down price control or price affirmation statutes dictating or requiring pricing in other states as constituting extraterritorial regulation. The Ninth Circuit recently concluded in

Canards, that "*Healy* and *Baldwin* are not applicable to a statute that does not dictate the price of a product and does not 't[ie] the price of its in-state products to out-of-state prices.'" 729 F.3d at 951, citing *Pharma. v. Walsh*, 538 U.S. at 669. Accordingly, neither *Healy* nor *Baldwin* support PhRMA here.

C. The Ordinance Is Not A "Direct Burden" Because Producers Can Elect Whether They Are Subject To It.

The Ninth Circuit recognized in *S.D. Myers*, 253 F.3d at 465, that an entity's ability to elect to be subjected to a local regulation is an important factor in determining whether that regulation is a "direct burden" on interstate commerce. At issue was an ordinance requiring contractors with San Francisco to provide nondiscriminatory benefits to employees with registered domestic partners. In rejecting the Commerce Clause challenge, the Ninth Circuit found it significant that "the Ordinance will affect an out-of-state entity only after that entity has affirmatively chosen to subject itself to the Ordinance by contracting with the City." *Id.* at 469.

The same is true here. Any Producer that declines to be subject to the Ordinance can elect not to sell, offer for sale, or distribute prescription drugs in Alameda. *See* ER 83 (Fact 8); ER 69 (Exhibit A, § 6.53.040.A) ("This Chapter shall apply only to a Producer whose Covered Drug is sold or distributed in Alameda County.").

D. Holding Producers Responsible For Disposal And Education Is Not A "Direct Burden."

PhRMA further claims that the Ordinance is a "direct burden" on interstate commerce because it requires interstate entities to conduct an entirely new business—waste disposal—and to perform an educational function informing Alameda residents about take-back programs, which PhRMA equates to being a "mouthpiece" for Alameda County. PhRMA Brief at 29 n.5 & 49.

The Ordinance provides that Producers can either perform Covered Drug collection themselves, or contract with product stewardship organizations for these services, just as Producers contract with wholesalers/distributors, advertisers, drug container/package manufacturers, and other suppliers and vendors. *See* ER 69 (Exhibit A, § 6.53.040.A.1 & .2). Producers are obviously knowledgeable about the dangers of disposing of unused chemicals or chemical residues resulting from manufacturing Covered Drugs, and hopefully dispose of that harmful waste at their own facilities in a careful and safe manner. Brief of Washington Legal Foundation and California Care Institute at 15, n.4. Of course, drug companies are also very experienced in disseminating public information, collectively spending nearly $11 billion in advertising in 2011 alone. ER 87 (Fact 35).

PhRMA's argument is basically that any local statute premised on the principle of "Extended Producer Responsibility"—*i.e.*, a local statute requiring manufacturers to remain responsible for the lifecycle of their products—is *per se*

invalid under the Commerce Clause. Contrary to PhRMA's suggestion, sound public policy dictates that manufacturers cannot use the Commerce Clause to insulate themselves from local regulations that require them to take responsibility for the waste disposal problems created by products from which they profit. Furthermore, PhRMA fails to cite any case in which a law was invalidated under the Commerce Clause because it required a regulated business to undertake an endeavor directly related to the harmful effects of its own products.

E. The Ordinance Does Not "Directly Burden" Interstate Commerce By Requiring Price Increases Anywhere.

PhRMA argues that the Ordinance "directly burdens" interstate commerce because "it expressly exempts local consumers from any point-of-sale fee related to collection and disposal costs," is "designed to exclusively benefit Alameda residents, and will be exclusively paid for by consumers outside of Alameda." PhRMA Brief at 43. While the Ordinance prohibits point-of-sale and point of disposal fees, it does *not* prohibit price increases for Covered Drugs sold in Alameda and certainly does not require out-of-county consumers to pick up the program's costs. *See* PhRMA Brief at 41 n.7.

More importantly, whether a regulated company can recoup its regulatory costs from anyone is not a concern of the dormant Commerce Clause. As the Second Circuit concluded in *Sorrell*, 272 F.3d at 111, the Commerce Clause is not concerned about profits:

> [T]hat manufacturers must bear some of the costs of the Vermont regulation in the form of lower profits does not cause the statute to violate the Commerce Clause. Such a burden is simply attributable to legitimate intrastate regulation.

Id. In fact, a dormant Commerce Clause analysis invariably involves evaluating the burden on the regulated companies or industry. Payment of unrecouped regulatory costs obviously affects profits, but "[t]he dormant Commerce Clause does not protect a particular company's profits." *Optometrists & Opticians*, 682 F.3d at 1152 n.11, citing *Exxon*, 437 U.S. at 127; *Pharma. v. Walsh*, 538 U.S. at 669-70, upheld rebates paid on specific drugs; by implication the cost of the rebates could not be recouped on the sale of such drugs. In fact, if recoupment of the cost burden were required in a regulation to avoid unconstitutionality, there would never be a burden to weigh under the *Pike* test because all costs would be passed on.

In addition, PhRMA advances the obviously false premise that the Ordinance requires PhRMA members to pass on any costs of compliance to consumers nationwide. PhRMA Brief at 43. Producers have the choice to pass on increased costs arising from any cause however they choose. They can also absorb the undisputed *de minimis* financial burden of the Ordinance. Based on Alameda County drug sales of $965 million in 2010, Alameda's estimate of the annual cost of compliance is a minuscule fraction of the revenue extracted by Producers from Alameda County. ER 86-87 (Facts 28, 30 and 34). Furthermore, it is undisputed

that the $670,000 difference between Alameda County's and PhRMA's estimate of annual Ordinance costs is "not material." ER 86 (Fact 30).

While PhRMA takes issue with the prohibition against a point-of-sale or point-of-disposal fee, such provisions are neither unique nor unconstitutional. In *AT&T Corp. v. Rudolph*, No. 06-16, 2007 U.S. Dist. LEXIS 13962, at *2-3 (E.D. Ky. Feb. 27, 2007), for example, the plaintiffs, which were various interexchange telecommunications service providers, challenged a gross revenue tax on service providers that prohibited providers from "collect[ing] the tax directly from the purchaser or separately stat[ing] the tax on the bill to the purchaser." In rejecting the plaintiffs' argument that the tax violated the Commerce Clause because it would necessarily have to be paid for by customers nationwide, the court concluded that the law at issue "only prohibits the telephone companies from *directly* recovering the [tax] from their Kentucky customers by way of a separately stated charge" and that the plaintiffs were permitted "to recover the cost . . . by raising the rates of only their Kentucky customers." *Id.* at *28.

As in *AT&T*, Producers can elect to recoup their modest disposal costs by increasing prices on Covered Drugs distributed and sold in the County. While PhRMA suggests that it cannot raise prices only in Alameda County, there is no evidence in the record that this is true. *See* PhRMA Brief at 41 n.7 (arguing that the cost of the Ordinance "will be 'felt almost entirely' by pharmaceutical

consumers nationwide."). Indeed, it seems farfetched that manufacturers who annually sell around $1 billion of products in Alameda County (ER 87, Fact 34) are powerless to extract even a penny or two more on each bottle of pills that is distributed and sold in the County.

Even if Producers' choice of distribution systems makes it difficult to raise prices on drugs distributed or sold in the County, Producers cannot invoke their chosen system to claim that Alameda's Ordinance is unconstitutional. In *Sorrell*, 272 F.3d at 110, out-of-state manufacturers argued that their production and distribution systems would make it difficult to comply with Vermont's labeling requirement. The court rejected this argument and observed that the claimed problem existed "only because the manufacturers are unwilling to modify their production and distribution systems. . . ." *Id.*

Thus, PhRMA's contention that the Ordinance will necessarily operate extraterritorially by affecting drug prices outside of Alameda assumes that Producers will elect to increase their out-of-County prices for Covered Drugs, which is a choice entirely within their control.

F. The Ordinance Will Not "Directly Burden" Interstate Commerce By "Thoroughly Stifling" The Market.

PhRMA argues that the Ordinance is a "direct burden" because "widespread adoption of Ordinance-like laws would 'stifle' the interstate market." PhRMA Brief at 44. PhRMA misleadingly omits that a statute is only problematic if its

widespread adoption would "*thoroughly stifle[]*" the market. *See Edgar v. MITE Corp.*, 457 U.S. 624, 642 (1982) (plurality opinion) (emphasis added). Notwithstanding their omission, PhRMA failed to present any evidence that the Ordinance, if widely adopted, will materially impede the flow of interstate commerce or affect sales or competition anywhere.

There is no evidence that adoption of a drug stewardship program in Alameda or anywhere else will materially affect the sale of prescription drugs inside or outside of Alameda County. There is no evidence that any county will "retaliate" against any other county because one county has a drug stewardship program and another does not. There is no evidence that any company will locate or relocate its operations because of any drug stewardship program in any state or county. As a result, similar ordinances or laws in other counties or states will not stifle interstate competition in any way.

PhRMA has offered no evidentiary basis on which this Court could conclude that competition or sales in the pharmaceutical industry, which enjoyed more than $2 trillion in revenue between 2005 and 2011, would be "thoroughly stifled" if the Ordinance, with its *de minimis* costs, were adopted by other local governments. *See* ER 85-87 (Facts 26 27, 30, 32 and 34). *See S.D. Myers*, 253 F.3d at 469 70 (holding the plaintiff had the burden of showing the challenged law would result in a direct burden). Nor is there any evidence that the cost of the EPR program in

Alameda County will increase if other jurisdictions adopt an EPR prescription drug program. And even if other local governments enacted similar EPR laws, PhRMA and their members would likely benefit from economies of scale and from their experience in complying with the Ordinance.

VII. The Ordinance Does Not Directly Regulate Interstate Commerce.

"Direct regulation occurs when a state law directly affects transactions that take place across state lines or entirely outside of the state's borders." *S.D. Myers*, 253 F.3d at 467, quoting *Valley Bank of Nevada v. Plus System, Inc.*, 914 F.2d 1186, 1189-90 (9th Cir. 1990); *see also Kleenwell*, 48 F.3d at 397.

PhRMA's reliance on *NCAA v. Miller*, 10 F.3d 633 (9th Cir. 1993), to support its position that the Ordinance is "extraterritorial" because it regulates activity that occurs entirely outside of the County is misplaced. First, the Ordinance does not regulate any activity that occurs entirely outside the County. Second, *NCAA* simply has no relevance to this case. There, the NCAA, a national sports organization with members that compete in all states, challenged as unconstitutional under the Commerce Clause a Nevada statute that would have required the NCAA to change its policies in all states to comply with the Nevada law. *Id*. at 638-39. The NCAA had a unique requirement for uniformity in its procedures in all states. *Id.* at 639. This Court rightly concluded that the Nevada law was in purpose and effect extraterritorial in its reach because it would have

required the NCAA to adhere to Nevada's procedures across the country. *Id*. Unlike the *NCAA*, PhRMA has not shown that the pharmaceutical industry has any similarity to the unique requirement for uniform enforcement in all states.

Similar arguments were rejected by the Ninth Circuit in *Valley Bank of Nevada v. Plus System, Inc.*, 914 F.2d at 1188 (9th Cir. 1990), which is consistent with the principle that a local government has the authority to protect its citizens by regulating non-local companies' conduct *within the locality*. In *Valley Bank*, a Nevada law provided that nationwide ATM networks could not prohibit Nevada banks from charging transaction fees to ATM cardholders who withdraw funds from Nevada banks' ATMs but whose accounts were with out of state banks. Plus Systems, Inc. ("Plus"), an owner and operator of a national network of ATMs, claimed that the Nevada law violated the Commerce Clause because it "directly regulated" interstate commerce since many of its member banks were located in states other than Nevada, resulting in the Nevada law regulating out-of-state entities. *Id*. at 1190-91.

The District Court granted summary judgment against Plus, and the Ninth Circuit affirmed, rejecting Plus's "direct regulation" argument:

> [Plus's] argument goes too far. Plus is claiming essentially that no state can prohibit companies from contracting in certain ways when one of the companies is from another state. At the extreme, this argument would mean that a state could make no rules to which commercial contracts with non-state-resident parties must conform.

Id. at 1190. The statute did not become an impermissible direct regulation simply because it affected non-Nevada banks' conduct within Nevada. *See also Exxon*, 437 U.S. at 127 ("[W]e cannot adopt appellant's novel suggestion that because the economic market for petroleum products is nationwide, no state has the power to regulate the retail marketing of gas.").

PhRMA's argument that the Ordinance is a "direct regulation" because most of its members are outside of Alameda County is indistinguishable from the argument asserted by Plus in *Valley Bank* and rejected by the Ninth Circuit and the argument asserted by PhRMA in *Pharma. v. Walsh* and rejected by the Supreme Court. Indeed, if PhRMA's argument were valid, local governments would be precluded from regulating the hazardous waste created by the pharmaceutical industry's products, which is fundamentally inconsistent with the well-established principle that "[w]aste disposal is both typically and traditionally a local government function." *United Haulers*, 550 U.S. at 344 (internal quotations omitted). Contrary to PhRMA's argument, the Ordinance is not an impermissible "direct burden" simply because it affects entities located outside Alameda that elect to sell, offer for sale, or distribute prescription drugs in the County.

VIII. Cost Shifting From the Public To the Private Sector Is Not A Violation Of the Dormant Commerce Clause.

PhRMA contends that the dormant Commerce Clause prohibits Alameda from shifting local County costs on to Producers through the Ordinance. In fact,

Alameda is not shifting costs; it is following the EPR cradle-to-grave model by placing the disposal costs of the product on those who manufacture the products.

Furthermore, shifting local costs is not a direct or impermissible burden under the dormant Commerce Clause. For example, as discussed above, in *Pharma. v. Walsh*, 538 U.S. at 654, the State of Maine required out-of-state prescription drug manufacturers to pay cash rebates to in-state pharmacies for the sale of certain drugs to low income consumers. This program, upheld by the Supreme Court, enabled Maine to reduce its Medicaid costs at the expense of drug manufacturers. *Id.* at 663-64.

Likewise, in *United Haulers*, 550 U.S. at 336, 346, a county required all waste collected in the jurisdiction to be processed at a government waste facility and set prices high enough to recover all government expense. Rather than finding a violation of the dormant *Commerce Clause*, the Supreme Court found the local ordinance gave "the Counties a convenient and effective way to finance" waste services. *Id*.

As Chief Justice Roberts wrote in *United Haulers*, "While 'revenue generation is not a local interest that can justify *discrimination* against interstate commerce,' we think it is a cognizable benefit for purposes of the *Pike* test." 550 U.S. at 346 quoting *Carbone*, 511 U.S. at 393. Justice Souter also observed in his dissent in *Carbone*, 511 U.S. at 429, that "Protection of the public fisc is a

legitimate local benefit directly advanced by the ordinance and quite unlike the generalized advantage to local businesses that we have condemned as protectionist in the past." Thus, the revenue generated by the Ordinance to finance local waste services is not prohibited by the Commerce Clause and is, in fact, a permissible benefit considered under the *Pike* test.

IX. Under *Pike*, The Undisputed Local Health, Safety And Environmental Benefits Of The Ordinance Clearly Outweigh Any Burden.

Because the Ordinance does not directly burden or regulate interstate commerce, discriminate against interstate commerce, or otherwise impermissibly favor in-state competitors over out-of-state competitors, the appropriate test for Commerce Clause purposes is *Pike*, 397 U.S. 137:

> Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.

Id. at 142. It is the burden of the party challenging the statute to establish that the burden on interstate commerce clearly exceeds the local benefits. *Kleenwell*, 48 F.3d at 399. Local "laws frequently survive this *Pike* scrutiny." *Kentucky*, 553 U.S. at 339.

In applying the *Pike* test, this Court should not consider less restrictive alternatives to the Ordinance because this case only involves an incidental burden to commerce. The Ninth Circuit recently confirmed in *Optometrists & Opticians*

that, while discriminatory laws are subject to "strict scrutiny," laws that are nondiscriminatory do not require strict scrutiny or consideration of less restrictive governmental alternatives. "This distinction is consistent with case law requiring the consideration of less restrictive alternatives *only when heightened scrutiny is required*." 682 F.3d at 1157, *citing Kentucky*, 553 U.S. at 338-39; emphasis added.

PhRMA has not established that any burden on interstate commerce clearly exceeds the Ordinance's local benefits. *"[T]he Ordinance's environmental, health and safety benefits are not contested for purpose[s] of the cross-motions for summary judgment."* ER 87 (Fact 37) (emphasis added). As recognized by both the Ninth Circuit and the Supreme Court, "regulations that touch upon safety . . . are those that 'the Court has been most reluctant to invalidate.'" *Kleenwell*, 48 F.3d at 401 n.11, quoting *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 670 (1981). Thus, "if safety justifications are not illusory, the Court will not second-guess legislative judgment about their importance in comparison with related burdens on interstate commerce." *Id.*

Compared with the important benefits of the Ordinance, the burden on interstate commerce is *de minimis*. The cost of the Ordinance, which Alameda estimates is about $530,000 per year, is to be fairly allocated by and among members of an industry (ER 86 (Facts 28 & 30)) that counts its County-revenues in hundreds-of-millions-of-dollars and its nationwide-revenues in hundreds-of-

billions-of-dollars. Even the $670,000 difference in the parties' annual cost estimates is stipulated to be immaterial. ER 86 (Fact 30).

By way of contrast, the Court in *Exxon* upheld a burden that involved requiring oil producers and refiners, all of which were out of state, to divest themselves of service stations they owned in the state. *Exxon*, 437 U.S. at 119-23. The logical alternative to avoid the regulation was for affected oil companies to keep the service stations but curtail all production and refining. Even that burden, which is onerous when compared with the Ordinance, was found to be constitutional. *See id.* at 125-126.

Overlooking the *Pike* test, PhRMA argues that, if the Ordinance is upheld, states can create EPR programs for discarded wine bottles, newspapers and other products that come from out-of-state. PhRMA Brief at 15. But these waste products have not yet been shown to present the special problems to health, safety and the environment. More importantly, *Pike* would require the benefits of such EPR programs to be weighed against the burdens on interstate commerce, if any. In this case, PhRMA did not (and cannot) meet its high burden to prove that the small burden of the Ordinance clearly exceeds the benefits.

X. Response To *Amici* Briefs.

Amicus briefs filed by the Chamber of Commerce of the United States of America ("Chamber") and the Washington Legal Foundation and California Health

Care Institute (collectively, "Foundation") take PhRMA's arguments to the extreme by ignoring the Stipulated Facts, asserting facts unsupported by evidence, relying on inapposite cases, and resting on a District of Columbia federal district court decision involving PhRMA that even PhRMA does not cite. *Amici's* arguments are for the most part disposed of above in response to PhRMA's Brief. Below, Alameda County provides some supplemental comments to *Amici's* scattergun arguments.

To set up the basis for almost all of their arguments, *Amici* assert that Producers have no relationship whatsoever with the County. Ignoring the Stipulated Facts that Producers market, sell, offer for sale, and distribute Covered Drugs in Alameda (ER 82-83, 86-87 (Facts 1, 7, 11, 29 and 33)), *Amici* use such phrases regarding the Producers' Covered Drugs as "ultimately find their way," "wind[] up being sold in" (Chamber at 2, 3), and "eventually found its way . . . into Alameda County." Foundation at 3. However, there is no evidence that Producers do not desire and intend their drugs to be sold in Alameda. Indeed, PhRMA and *Amici* stress that Producers sell nationally, including to national drug store chains that have stores in Alameda County. ER 84 (Fact 18).

It is inconceivable that Producers would not intend to sell their products in the billion dollar market in Alameda. In addition, drug companies have a physical presence in Alameda (ER 84 (Facts 12-14)), and approximately $3 billion of

prescription drugs are manufactured in the County. ER 84 (Fact 17). *Amici's* argument that Producers cannot be regulated because most, or all, of them are outside the County has already been rejected by the Supreme Court in *Pharma. v. Walsh*, 538 U.S. 644, and other cases discussed above.

Amici claim, contrary to the Stipulated Facts, that the Ordinance will cause Producers "to spend millions of dollars establishing a collection and education program" (Chamber at 5) and that there will be a "multi-million dollar obligation potentially imposed on each Producer." (Foundation at 22.) *See also* Chamber at 15 ("bear millions of dollars in costs"). Of course, there is no evidentiary support for these wild claims and, as discussed above, the parties' stipulated estimates demonstrate *de minimis* aggregate costs (ER 85-86 (Facts 26, 27 and 30)) and minimal average costs per Producer. Similarly, Foundation's argument that costs will not be fairly apportioned among Producers (Foundation at 20) is controverted by the Ordinance and ignores the parties' stipulation to the contrary. ER 82 (Fact 3).

Amici argue that, if Producers want to avoid being regulated in Alameda County, it would be burdensome "to ensure that their products never enter the County." Chamber at 18. As with their other arguments, there is no evidence to support this assertion. Moreover, it strains credibility to suggest that Producers would abandon the lucrative Alameda County market just to avoid the *de minimis*

costs of the Ordinance, which (as discussed above) are a tiny fraction of Alameda County pharmaceutical sales revenue.

Amici also stress that Producers cannot recoup their costs through point-of-sale or point-of-disposal fees. Foundation goes further, stating without evidence, that "the County has taken steps to ensure that the producers are not permitted to pass their compliance costs on to those who benefit from the program." Foundation at 3 and 12 ("barring Producers from seeking to recoup those costs"). Of course, this is not true because the Ordinance does not prohibit Producers from raising prices on products sold into Alameda County. Moreover, as demonstrated above, this argument is irrelevant since cost recoupment is of no concern to the dormant Commerce Clause, which is indifferent to company profits if there is no protectionist discrimination.

No evidence supports *Amici's* arguments that Producers have no way of knowing how much of their product is sold in Alameda. Common sense suggests that distributors, wholesalers, and chain retailers keep records of the sale of specific drugs in specific places in order to supply the demand. Prescription drugs sales are also carefully documented, starting with written prescriptions dispensed at specific pharmacies to named individuals.

Just as PhRMA argued without support, *Amici* argue that Alameda County "already has established a program that adequately addresses the environmental,

health, and safety concerns" that are addressed by the Ordinance. Foundation at 8. Whether there was a pre-existing program is irrelevant to Commerce Clause analysis. *Hughes*, 426 U.S. at 809. Even if Alameda County already performed all of the Ordinance's functions, as Chief Justice Roberts wrote in *United Haulers*, 50 U.S. at 346, shifting these costs to the private sector is a benefit under the *Pike* test.

Amici vigorously argue that "retail pharmacies and Producers should be deemed 'substantially similar' . . . ." Foundation at 14-15. However, pharmacies do not compete with manufacturers at any level; pharmacies only retail multiple manufacturers' products. Nothing in the Ordinance enables pharmacies to gain a competitive advantage over Producers, so there is no arguable dormant Commerce Clause issue.

Like PhRMA, *Amici* argue that, if Alameda is allowed to create an EPR program for prescription drugs, other counties may do so. As discussed above, this is not a Commerce Clause concern. Whether other counties or states adopt such a program will not interfere with the free flow of commerce, and the Ordinance will not cause any other county to retaliate against Alameda County, because it has no effect on any other county. "Balkanization" of commerce is simply not implicated.

Amici argue that some Producers may not comply with the Ordinance's requirements. Foundation at 22 n. 8. This is not a Commerce Clause issue. Moreover, the fact that a law might not be perfectly administered, or that some

regulated companies might not comply, is not a cognizable basis for invalidating a law under the Commerce Clause.

Amici also argue that, because most drug companies are located out of the County, the pharmaceutical industry does not have enough political clout to influence Alameda County's Supervisors. Foundation at 11 ("no interest group within Alameda County has an economic incentive to oppose" the Ordinance). The Supreme Court has rejected the argument that the mere out-of-state location of regulated companies makes a local law unconstitutional. *See Exxon*, 437 U.S. at 119-26; *CTS*, 481 U.S. at 88. This argument also ignores that three major pharmaceutical companies are headquartered or have their principal places of business in Alameda, two manufacturers in Alameda County account for approximately $3 billion of all prescription drugs sold nationally, and 22 companies are licensed to manufacture drugs in the County. ER 84 (Facts 12, 13, 14 and 17).

It is axiomatic that a robust business climate is essential to the economic well-being of a county. The elected Supervisors are responsible for taking into account the economic interests of the entire County, including its business and manufacturing base and its inhabitants. Moreover, *Amici's* suggestion that there is no political incentive to keep the costs of the program down (Foundation at 27, 28) ignores the terms of the Ordinance. The Ordinance gives Producers the power to

design and operate an efficient EPR program for Covered Drugs. Producers therefore have every incentive to provide the least expensive effective EPR program. The County has no incentive to require Producers to incur more cost than necessary.

Amici argue that the Ordinance regulates commerce wholly outside of Alameda County. Chamber at 11. There are no facts to support this argument, and the parties have stipulated to the contrary. ER 83 (Fact 9). The Ordinance does not dictate any transaction anywhere between a Producer and a wholesaler or a retail chain. Producers will continue to do business exactly as they have done everywhere in the United States. The only change required by the Ordinance is that Producers establish an EPR program in Alameda for the safe disposal of their unwanted prescription drugs.

The Chamber cites *Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56 (D.D.C. 2005), a case that has no relevance here. PhRMA itself does not rely on this case, which was litigated in the same jurisdiction where PhRMA and its current counsel are located. In that case, the district court found a price control regulation unconstitutional because it "applied to transactions between manufacturers and wholesalers that occur wholly out of state." *Id*. at 68. The Ordinance, however, does not apply to any out-of-County transaction.

Finally, *Amici* concede the obvious: manufacturers "have significant technical expertise relevant to the collection of unwanted drugs." Foundation at 15, n.4. This is one of many reasons Producers should be required to use their expertise to prevent adverse health, safety and environmental harm by assuring proper disposal of unwanted or unused prescription drugs.

CONCLUSION

For all of the foregoing reasons, the Ordinance is constitutional, and the District Court's judgment should be affirmed.

Dated: January 15, 2014

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the enlargement of brief size granted by court order dated December 24, 2013. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6). This brief is 14,976 words, excluding the portions exempted by Fed. R. App. P. 32(a)(7)(B)(iii), if applicable.

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STATEMENT OF RELATED CASES

Pursuant to Circuit Rule 28-2.6, Appellees state that:

1. There is no appeal that arises out of the same case (or any consolidated case) in the district court;

2. No appeal that concerns the case being briefed was previously taken to this Court;

3. They are unaware of any case that raises the same or closely-related issues that are on appeal to this Court; and

4. They are unaware of any case that is on appeal to this Court and which involves the same transaction or event at issue in this case.

Dated: January 15, 2014

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on January 15, 2014.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: January 15, 2014

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STATUTORY ADDENDUM

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U.S. Constitution, Article 1, Section 8:

The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States;

To borrow Money on the credit of the United States;

To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes;

To establish an uniform Rule of Naturalization, and uniform Laws on the subject of Bankruptcies throughout the United States;

To coin Money, regulate the Value thereof, and of foreign Coin, and fix the Standard of Weights and Measures;

To provide for the Punishment of counterfeiting the Securities and current Coin of the United States;

To establish Post Offices and post Roads;

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;

To constitute Tribunals inferior to the supreme Court;

To define and punish Piracies and Felonies committed on the high Seas, and Offences against the Law of Nations;

To declare War, grant Letters of Marque and Reprisal, and make Rules concerning Captures on Land and Water;

To raise and support Armies, but no Appropriation of Money to that Use shall be for a longer Term than two Years;

To provide and maintain a Navy;

To make Rules for the Government and Regulation of the land and naval Forces;

To provide for calling forth the Militia to execute the Laws of the Union, suppress Insurrections and repel Invasions;

To provide for organizing, arming, and disciplining, the Militia, and for governing such Part of them as may be employed in the Service of the United States, reserving to the States respectively, the Appointment of the Officers, and the Authority of training the Militia according to the discipline prescribed by Congress;

To exercise exclusive Legislation in all Cases whatsoever, over such District (not exceeding ten Miles square) as may, by Cession of particular States, and the Acceptance of Congress, become the Seat of the Government of the United States, and to exercise like Authority over all Places purchased by the Consent of the Legislature of the State in which the Same shall be, for the Erection of Forts, Magazines, Arsenals, dock-Yards, and other needful Buildings;--And

To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof.

California Food & Agriculture Code Section 12841.4:

(a) Every registrant of any production agricultural- or structural-use pesticide product sold for use in this state that is packaged in rigid, nonrefillable, high-density polyethylene (HDPE) containers of 55 gallons or less shall establish a recycling program, or demonstrate participation in a recycling program to ensure HDPE containers are recycled. Container recycling must comply with the American National Standards Institute American Society of Agriculture and Biological Engineers Standard S596, entitled Recycling Plastic Containers from Pesticides and Pesticide-Related Products, as published in February 2006. The records required by these standards shall be maintained for three years and shall be subject to audit by the director.

(b) Any registrant who is required to establish or participate in a recycling program pursuant to this section shall provide to the director, at least annually, a document certifying that this requirement has been met.

(c)

(1) The director may adopt regulations to carry out the purposes of this section. Upon a federal pesticide container recycling program being adopted, the director may adopt regulations to conform to the federal program.

(2) It is the intent of the Legislature in enacting this section that any regulatory standards adopted by the department shall be at least as stringent as those standards referred to in subdivision (a).

(d) Commencing September 1, 2010, the department shall estimate a recycling rate for pesticide containers and propose suggestions for program improvements and post this information annually on its Internet Web site.

California Health & Safety Code Section 25982:

A product may not be sold in California if it is the result of force feeding a bird for the purpose of enlarging the bird's liver beyond normal size.

California Public Resources Code Sections 42970-83:

42970.

The purpose of this chapter is to increase the amount of postconsumer carpet that is diverted from landfills and recycled into secondary products or otherwise managed in a manner that is consistent with the state's hierarchy for waste management practices pursuant to Section 40051.

42971.

For purposes of this chapter, and unless the context otherwise requires, the definitions in this section govern the construction of this chapter:

(a) "Brand" means a name, symbol, word, or mark that identifies the carpet, rather than its components, and attributes the carpet to the owner or licensee of the brand as the manufacturer.

(b) "CARE" means the Carpet America Recovery Effort, a third-party nonprofit carpet stewardship organization incorporated as a nonprofit corporation pursuant to Section 501(c)(3) of Title 26 of the United States Code in 2002 and established to increase the reclamation and stewardship of postconsumer carpet.

(c) "CARE MOU" means the 2012 Memorandum of Understanding for Carpet Stewardship, as to be negotiated among the carpet industry, states, and nongovernmental organization stakeholders as a successor to the 2002 memorandum of understanding.

(d)

(1) "Carpet" means a manufactured article that is used in commercial or residential buildings affixed or placed on the floor or building walking surface as a decorative or functional building interior feature and that is primarily constructed of a top visible surface of synthetic face fibers or yarns or tufts attached to a backing system derived from synthetic or natural materials.

(2) "Carpet" includes, but is not limited to, a commercial or a residential broadloom carpet or modular carpet tiles.

(3) "Carpet" does not include a rug, pad, cushion, or underlayment used in conjunction with, or separately from, a carpet.

(e)

(1) "Carpet stewardship organization" or "organization" means either of the following:

(A) An organization appointed by one or more manufacturers to act as an agent on behalf of the manufacturer to design, submit, and administer a carpet stewardship plan pursuant to this chapter.

(B) A carpet manufacturer that complies with this chapter as an individual manufacturer.

(2) Notwithstanding paragraph (1), until April 1, 2015, CARE shall be the sole carpet stewardship organization pursuant to subparagraph (A) of paragraph (1).

This paragraph does not restrict the option of an individual carpet manufacturer to comply with this chapter as a carpet stewardship organization, on and after January 1, 2011, pursuant to subparagraph (B) of paragraph (1).

(f) "Carpet stewardship plan" or "plan" means a plan written by an individual manufacturer or a carpet stewardship organization, on behalf of one or more manufacturers, that includes all of the information required by Section 42972.

(g) "Consumer" means a purchaser, owner, or lessee of carpet, including a person, business, corporation, limited partnership, nonprofit organization, or governmental entity.

(h) "Department" means the Department of Resources Recycling and Recovery.

(i) "Label" means a graphic representation of three chasing arrows with a carpet roll inside the arrows, or an alternative design, designed by CARE, after consultation with retailers and wholesalers, and approved by the department for use on all invoices or functionally equivalent billing documents pursuant to subparagraph (C) of paragraph (3) of subdivision (c) of Section 42972.

(j) "Manufacturer" means, with regard to a carpet that is sold, offered for sale, or distributed in the state any of the following:

(1) The person who manufactures the carpet and who sells, offers for sale, or distributes that carpet in the state under that person's own name or brand.

(2) If there is no person who sells, offers for sale, or distributes the carpet in the state under the person's own name or brand, the manufacturer of the carpet is the owner or licensee of a trademark or brand under which the carpet is sold or distributed in the state, whether or not the trademark is registered.

(3) If there is no person who is a manufacturer of the carpet for the purpose of paragraphs (1) and (2), the manufacturer of that carpet is the person who imports the carpet into the state for sale or distribution.

(k) "Postconsumer carpet" means carpet that is no longer used for its manufactured purpose.

(l) "Recycling" means the process, consistent with Section 40180, of converting postconsumer carpet into a useful product that meets the quality standards necessary to be used in the marketplace.

(m) "Retailer" means a person who offers new carpet in a retail sale, as defined in Section 6007 of the Revenue and Taxation Code, including a retail sale through any means, including remote offerings such as sales outlets, catalogs, or an Internet Web site or other similar electronic means.

(n) "Sell" or "sales" means a transfer of title of a carpet for consideration, including a remote sale conducted through a sales outlet, catalog, Internet Web site or similar electronic means. For purposes of this chapter, "sell" or "sales" includes a lease through which a carpet is provided to a consumer by a manufacturer, wholesaler, or retailer.

(o) "Wholesaler" means a person who offers new carpet for sale in this state in a sale that is not a retail sale, as defined in Section 6007 of the Revenue and Taxation Code, and in which the carpet is intended to be resold.

42972.

(a) On or before September 30, 2011, a manufacturer of carpets sold in this state shall, individually or through a carpet stewardship organization, submit a carpet stewardship plan to the department that will do all of the following:

(1) Achieve the purposes of this chapter, as described in Section 42970, and meet the requirements of Section 42975.

(2) Include goals that, to the extent feasible based on available technology and information, increase the recycling of postconsumer carpet, increase the diversion of postconsumer carpets from landfills, increase the recyclability of carpets, and incentivize the market growth of secondary products made from postconsumer carpet. The goals established in the plan shall, at a minimum, be equal to the goals established in the CARE MOU, if it has been adopted at the time the plan is submitted to the department.

(3) Describe proposed measures that will enable the management of postconsumer carpet in a manner consistent with the state's solid waste management hierarchy, including, but not limited to, source reduction, source separation and processing to segregate and recover recyclable materials, and environmentally safe management of materials that cannot feasibly be recycled.

(4) Include a funding mechanism, consistent with subdivision (c), that provides sufficient funding to carry out the plan, including the administrative, operational, and capital costs of the plan, payment of fees pursuant to Section 42977, and incentive payments that will advance the purposes of this chapter.

(5) Include education and outreach efforts to consumers, commercial building owners, carpet installation contractors, and retailers to promote their participation in achieving the purposes of the carpet stewardship plan as described in paragraph (1). These education and outreach materials may include, but are not limited to, any of the following:

(A) Signage that is prominently displayed and easily visible to the consumer.

(B) Written materials and templates of materials for reproduction by retailers to be provided to carpet installation contractors and consumers at the time of purchase or delivery or both.

(C) Promotional materials or activities, or both, that explain the purpose of carpet stewardship and the means by which it is being carried out.

(6) Include a process by which the financial activities of the organization or individual manufacturer that are related to implementation of the plan will be subject to an independent audit, which may be reviewed by the department.

(b) The plan prepared pursuant to this section shall be designed to accept and manage all suitable postconsumer carpet, regardless of polymer type or primary materials of construction.

(c)

(1) The funding mechanism required pursuant to paragraph (4) of subdivision (a) shall establish and provide for, on and after January 1, 2013, a carpet stewardship assessment per unit of carpet sold in the state in an amount that cumulatively will adequately fund the plan and be consistent with the purposes of the chapter. The assessment shall be remitted to the carpet stewardship organization on a quarterly basis and the carpet stewardship organization may expend the assessment only to carry out the plan.

(2) The amount of the assessment and the anticipated revenues from the assessment shall be specified in the plan and shall be approved by the department as part of the plan. The amount of the assessment shall be sufficient to meet, but not exceed, the anticipated cost of carrying out the plan. The amount of the assessment shall not create an unfair advantage in the marketplace.

(3) The assessment established pursuant to this subdivision and Section 42972.5 is exempt from the taxes imposed by Part 1 (commencing with Section 6001) of Division 2 of the Revenue and Taxation Code and shall meet both of the following requirements:

(A) The assessment shall be added by a manufacturer to the purchase price of all carpet sold by manufacturers to a California retailer or wholesaler or otherwise sold for use in the state. The assessment shall be clearly visible on invoices or functionally equivalent billing documents as a separate line item and shall be accompanied by a brief description of the assessment or a label approved by the department.

(B) Each retailer and wholesaler shall add the assessment to the purchase price of all carpet sold in the state. The assessment shall be clearly visible on invoices or functionally equivalent billing documents as a separate line item and shall be accompanied by a brief description of the assessment or a label approved by the department.

(d) A carpet stewardship organization that submits a plan pursuant to this section shall consult with retailers and wholesalers in the development of the plan, in order to minimize the impacts of the plan on retailers and wholesalers.

(e) A carpet stewardship organization shall notify the department within 30 days after instituting a significant or material change to an approved carpet stewardship plan.

42972.5.

(a) Notwithstanding paragraph (1) of subdivision (c) of Section 42972, on and after July 1, 2011, but not on or after January 1, 2013, a manufacturer of carpet shall add a carpet stewardship assessment of five cents ($0.05) per square yard to the purchase price of all carpet sold in the state by that manufacturer. The assessment added pursuant to this subdivision shall be remitted on a quarterly basis, as appropriate, to CARE or be retained by the individual manufacturer referred to in subparagraph (B) of paragraph (1) of subdivision (d) of Section 42971, for expenditure pursuant to subdivision (b).

(b) Prior to approval of a carpet stewardship plan, CARE or an individual manufacturer shall spend revenues from the assessment imposed pursuant to subdivision (a) only to implement early action measures that are consistent with the purposes of this chapter and that are designed to achieve measurable improvements in the landfill diversion and recycling of postconsumer carpet.

42973.

(a)

(1) Within 60 days after the department receives a plan submitted pursuant to Section 42972, it shall review the plan, determine whether it complies with Section 42972, and notify the submitter of its decision to approve or not approve the plan.

(2) On or after April 1, 2015, an organization appointed by one or more manufacturers to act as an agent on behalf of the manufacturer to design, submit,

and administer a carpet stewardship plan pursuant to this chapter may submit a plan to the department pursuant to Section 42972 and that plan may be approved by the department, subject to the requirements of paragraph (1), only if the department makes both of the following findings:

(A) The plan will not have the effect of reducing the level of diversion and recycling of postconsumer carpet that has been achieved pursuant to this chapter at the time the department reviews the plan.

(B) The amount of the assessment in the plan will not create an unfair advantage in the marketplace for one or more of the companies in the organization.

(b) If the department does not approve the plan, it shall describe the reasons for its disapproval in the notice. The submitter may revise and resubmit the plan within 60 days after receiving notice of disapproval and the department shall review and approve or not approve the revised plan within 60 days after receipt. Any plan not approved by March 31, 2012, shall be out of compliance with this chapter and the submitter of the plan is subject to the penalties specified in Section 42978 until the plan is approved by the department.

42974.

(a) The department shall enforce this chapter.

(b) On and after April 1, 2012, a manufacturer, wholesaler, or retailer that offers a carpet for sale in this state, or who offers a carpet for promotional purposes in this state, is not in compliance with this chapter and is subject to penalties pursuant to Section 42978, if the carpet is not subject to a plan that is submitted by an organization that includes the manufacturer of that carpet, which plan has been approved by the department pursuant to Section 42973.

(c)

(1) On July 1, 2012, and not later than January 1 and July 1annually thereafter, the department shall post a notice on its Internet Web site listing manufacturers that are in compliance with this chapter.

(2) A manufacturer that is not listed on the department's Internet Web site pursuant to this subdivision, but demonstrates to the satisfaction of the department that the manufacturer is in compliance with this chapter before the next notice is required to be posted, may request a certification letter from the department stating

that the manufacturer is in compliance. The letter shall constitute proof of compliance with this chapter.

(d) A wholesaler or retailer that distributes or sells carpet shall monitor the department's Internet Web site to determine if the sale of a manufacturer's carpet is in compliance with the requirements of this chapter. Notwithstanding Section 42978, a wholesaler or retailer otherwise in compliance with this chapter shall be deemed in compliance with this section if, on the date the wholesaler or retailer ordered or purchased carpet, the manufacturer was listed as a compliant manufacturer on the department's Internet Web site.

42975.

(a) In order to achieve compliance with this chapter, a carpet stewardship organization shall, on or before July 1, 2013, and annually thereafter, demonstrate to the department that it has achieved continuous meaningful improvement in the rates of recycling and diversion of postconsumer carpet subject to its stewardship plan and in meeting the other goals included in the organization's plan pursuant to paragraph (2) of subdivision (a) of Section 42972. In determining compliance, the department shall consider all of the following:

(1) The baseline rate of compliance against which the demonstrated improvement is compared.

(2) The goals included in the CARE MOU.

(3) Information provided in the organization's report to the department pursuant to Section 42976.

(b) If more than one organization submits a carpet stewardship plan pursuant to this chapter, the department shall use information submitted by the organization in its annual report pursuant to Section 42976 to determine to what extent the recycling and diversion rates and the achievement of the other goals included in the plan are attributable to each organization and shall determine compliance with this chapter accordingly.

42976.

On or before July 1, 2013, and each year thereafter, a manufacturer of carpet sold in the state shall, individually or through a carpet stewardship organization, submit to the department a report describing its activities to achieve the purposes

of this chapter, as described in Section 42970, and to comply with Section 42975. At a minimum, the report shall include all of the following:

(a) The amount of carpet sold by square yards and weight, in the state during the reporting period. A carpet stewardship organization with more than one manufacturer may use average weight.

(b) The amount of postconsumer carpet recycled, by weight, during the reporting period.

(c) The amount of postconsumer carpet recovered but not recycled, by weight, and its ultimate disposition.

(d) The total cost of implementing the carpet stewardship plan.

(e) An evaluation of the effectiveness of the carpet stewardship plan, and anticipated steps, if needed, to improve performance.

(f) Examples of educational materials that were provided to consumers during the reporting period.

42977.

(a) The carpet stewardship organization submitting a carpet stewardship plan shall pay the department a quarterly administrative fee. The department shall set the fee at an amount that, when paid by every carpet stewardship organization that submits a carpet stewardship plan, is adequate to cover the department's full costs of administering and enforcing this chapter, including any program development costs or regulatory costs incurred by the department prior to carpet stewardship plans being submitted. The department may establish a variable fee based on relevant factors, including, but not limited to, the portion of carpets sold in the state by members of the organization compared to the total amount of carpet sold in the state by all organizations submitting a carpet stewardship plan.

(b) The total amount of fees collected annually pursuant to this section shall not exceed the amount necessary to recover costs incurred by the department in connection with the administration and enforcement of the requirements of this chapter.

(c) The department shall identify the direct development or regulatory costs it incurs pursuant to this chapter prior to the submittal of a carpet stewardship plan and shall establish a fee in an amount adequate to cover those costs, which shall be

paid by a carpet stewardship organization that submits a carpet stewardship plan. The fee established pursuant to this subdivision shall be paid pursuant to the schedule specified in subdivision (d).

(d) A carpet stewardship organization subject to this section shall pay a quarterly fee to the department to cover the administrative and enforcement costs of the requirements of this chapter pursuant to subdivision (a) on or before July 1, 2012, and every three months thereafter and the applicable portion of the fee pursuant to subdivision (c) on July 1, 2012, and every three months thereafter through July 1, 2014. Each year after the initial payment, the total amount of the administrative fees paid for a calendar year may not exceed 5 percent of the aggregate assessments collected for the preceding calendar year.

(e) The department shall deposit the fees collected pursuant to this section into the Carpet Stewardship Account created pursuant to Section 42977.1.

42977.1.

(a) The Carpet Stewardship Account and the Carpet Stewardship Penalty Subaccount are hereby established in the Integrated Waste Management Fund.

(b) All fees collected by the department pursuant to this article shall be deposited in the Carpet Stewardship Account and may be expended by the department, upon appropriation by the Legislature, to cover the department's costs to implement this chapter.

(c) All civil penalties collected pursuant to this article shall be deposited in the Carpet Stewardship Penalty Subaccount and may be expended by the department, upon appropriation by the Legislature, to cover the department's costs to implement this chapter.

42978.

(a) A civil penalty up to the following amounts may be administratively imposed by the department on any person who is in violation of any provision of this chapter:

(1) One thousand dollars ($1,000) per day.

(2) Ten thousand dollars ($10,000) per day if the violation is intentional, knowing, or negligent.

(b) In assessing or reviewing the amount of a civil penalty imposed pursuant to subdivision (a) for a violation of this chapter, the department or the court shall consider all of the following:

(1) The nature and extent of the violation.

(2) The number and severity of the violation or violations.

(3) The economic effect of the penalty on the violator.

(4) Whether the violator took good faith measures to comply with this chapter and the period of time over which these measures were taken.

(5) The willfulness of the violator's misconduct.

(6) The deterrent effect that the imposition of the penalty would have on both the violator and the regulated community.

(7) Any other factor that justice may require.

42979.

(a) This chapter does not limit, supersede, duplicate, or otherwise conflict with the authority of the Department of Toxic Substances Control under Section 25257.1 of the Health and Safety Code to fully implement Article 14 (commencing with Section 25251) of Chapter 6.5 of Division 20 of the Health and Safety Code, including the authority of the department to include a carpet in a product registry adopted pursuant to that article.

(b) Notwithstanding subdivision (a), the Department of Toxic Substances Control shall fully consider the measures taken by the carpet industry pursuant to this chapter, and the results of those measures, when considering whether to include carpet in a product registry adopted pursuant to, or to otherwise regulate carpet pursuant to, Article 14 (commencing with Section 25251) of Chapter 6.5 of Division 20 of the Health and Safety Code.

42980.

(a) On or before January 1, 2014, the department and the Department of General Services shall complete a study that examines the specifications for carpet purchases by the state, as provided in the American National Standards Institute (NSF/ANSI) 140-2009 Standard, Platinum Level, as in effect on January 1, 2011 or the most current version in effect, and shall submit the study to the Governor

and the Legislature pursuant to Section 9795 of the Government Code, including recommendation for any appropriate changes to that standard. In examining the standard and recommending changes to the standard, the department and the Department of General Services shall consider all of the following:

(1) Any changes to the standard that would further the purpose of this chapter.

(2) Any changes to the standard that would improve the environmental sustainability of carpet purchased by the state.

(3) The life-cycle impacts of proposed changes to the standard.

(4) The impacts of the proposed changes to the standard on source reduction.

(5) The impacts of the proposed changes to the standard on the recyclability of carpet.

(6) Economic and technological barriers to the proposed changes to the standard.

(b) The department and Department of General Services shall hold at least one workshop to receive comments from interested stakeholders prior to the completion of the study.

(c) Pursuant to Section 10231.5 of the Government Code, this section is repealed on January 1, 2018.

42981.

(a) Except as provided in subdivision (b), any action by a carpet stewardship organization or its members that relates to any of the following is not a violation of the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), the Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code), or the Unfair Competition Law (Chapter 5 (commencing with Section 17200) of Part 2 of Division 7 of the Business and Professions Code):

(1) The creation, implementation, or management of a carpet stewardship plan approved by the department pursuant to Section 42973 and the types or quantities of carpet being recycled or otherwise managed as described in Section 42970.

(2) The cost and structure of an approved carpet stewardship plan.

(3) The establishment, administration, or disbursement of a carpet stewardship assessment as described in Section 42972 or 42972.5.

(b) Subdivision (a) does not apply to an agreement that does any of the following:

(1) Fixes a price of or for carpet, except for any agreement related to a carpet stewardship assessment pursuant to Section 42972.5 or to a carpet stewardship plan approved by the department and otherwise in accordance with this chapter.

(2) Fixes the output of production of carpet.

(3) Restricts the geographic area in which, or customers to whom, carpet will be sold.

42982.

The Department of General Services shall, to the extent feasible and within existing resources, take appropriate steps, including, but not limited to, revising relevant procurement rules, to ensure that postconsumer carpet that is removed from state buildings is managed in a manner consistent with the purpose of this chapter.

42983.

It is the intent of the Legislature to review any federal law that has the purpose of managing postconsumer carpet in a manner consistent with this chapter and to consider the extent to which the program created by that federal law will, at a minimum, achieve the same levels of landfill diversion and recycling of postconsumer carpet in California as this chapter.

California Public Resources Code Sections 48700-06:

48700.

The purpose of the architectural paint recovery program established pursuant to this chapter is to require paint manufacturers to develop and implement a program to collect, transport, and process postconsumer paint to reduce the costs and environmental impacts of the disposal of postconsumer paint in this state.

48701.

For purposes of this chapter, the following terms have the following meanings:

(a) "Architectural paint" means interior and exterior architectural coatings, sold in containers of five gallons or less for commercial or homeowner use, but does not include aerosol spray paint or coatings purchased for industrial or original equipment manufacturer use.

(b) "Consumer" means a purchaser or owner of architectural paint, including a person, business, corporation, limited partnership, nonprofit organization, or governmental entity.

(c) "Department" means the Department of Resources Recycling and Recovery.

(d) "Distributor" means a person that has a contractual relationship with one or more manufacturers to market and sell architectural paint to retailers.

(e) "Manufacturer" means a manufacturer of architectural paint.

(f) "Postconsumer paint" means architectural paint not used by the purchaser.

(g) "Retailer" means a person that sells architectural paint in the state to a consumer. A sale includes, but is not limited to, transactions conducted through sales outlets, catalogs, or the Internet or any other similar electronic means.

(h) "Stewardship organization" means a nonprofit organization created by the manufacturers to implement the architectural paint stewardship program described in Section 48703.

48702.

(a) A manufacturer of architectural paint sold in this state shall, individually or through a stewardship organization, submit an architectural paint stewardship plan to the department to develop and implement a recovery program to reduce the generation of postconsumer architectural paint, promote the reuse of postconsumer architectural paint, and manage the end-of-life of postconsumer architectural paint, in an environmentally sound fashion, including collection, transportation, processing, and disposal.

(b)

(1) A manufacturer or retailer shall not sell or offer for sale in this state architectural paint to any person in this state unless the manufacturer is in compliance with this chapter.

(2) The sales prohibition in paragraph (1) shall be effective on the 120th day after the notice described in subdivision (c) is posted on the department's Internet Web site, and shall apply to any manufacturer that is not listed on the department's Internet Web site, and shall remain in effect until the manufacturer is listed on the department's Internet Web site or can demonstrate compliance as described in paragraph (2) of subdivision (c).

(c)

(1) On July 1, 2012, or upon the date the first plan is approved, whichever date is earlier, the department shall post on its Internet Web site a list of manufacturers for which the department has approved a plan pursuant to subdivision (a) of Section 48704. The department shall update this posting no less than once every six months thereafter. On and after April 1, 2013, the department shall post a notice on its Internet Web site listing manufacturers that are in compliance with this chapter pursuant to subdivision (b) of Section 48705 and shall update this posting no less than once every six months.

(2) A manufacturer that is not listed on the department's Internet Web site pursuant to this section, but demonstrates to the satisfaction of the department that it is in compliance with this chapter before the next notice is required to be posted pursuant to this section, may request a certification letter from the department stating that the manufacturer is in compliance. The manufacturer who receives that letter shall be deemed to be in compliance with this chapter.

(d) A wholesaler or a retailer that distributes or sells architectural paint shall monitor the department's Internet Web site to determine if the sale of a manufacturer's architectural paint is in compliance with this chapter.

48703.

(a) On or before April 1, 2012, a manufacturer or designated stewardship organization shall submit an architectural paint stewardship plan to the department.

(b)

(1) The plan shall demonstrate sufficient funding for the architectural paint stewardship program as described in the plan, including a funding mechanism for securing and dispersing funds to cover administrative, operational, and capital costs, including the assessment of charges on architectural paint sold by manufacturers in this state.

(2) The funding mechanism shall provide for an architectural paint stewardship assessment for each container of architectural paint sold by manufacturers in this state and the assessment shall be remitted to the stewardship organization, if applicable.

(3) The architectural paint stewardship assessment shall be added to the cost of all architectural paint sold to California retailers and distributors, and each California retailer or distributor shall add the assessment to the purchase price of all architectural paint sold in the state.

(4) The architectural paint stewardship assessment shall be approved by the department as part of the plan, and shall be sufficient to recover, but not exceed, the cost of the architectural paint stewardship program. The plan shall require that any surplus funds be put back into the program to reduce the costs of the program, including the assessment amount.

(c) The plan shall address the coordination of the architectural paint stewardship program with existing local household hazardous waste collection programs as much as this is reasonably feasible and is mutually agreeable between those programs.

(d) The plan shall include goals established by the manufacturer or stewardship organization to reduce the generation of postconsumer paint, to promote the reuse of postconsumer paint, and for the proper end-of-life management of postconsumer paint, including recovery and recycling of postconsumer paint, as practical, based on current household hazardous waste program information. The goals may be revised by the manufacturer or stewardship organization based on the information collected for the annual report.

(e) The plan shall include consumer, contractor, and retailer education and outreach efforts to promote the source reduction and recycling of architectural paint. This information may include, but is not limited to, developing, and updating as necessary, educational and other outreach materials aimed at retailers of architectural paint. These materials shall be made available to the retailers. These materials may include, but are not limited to, one or more of the following:

(1) Signage that is prominently displayed and easily visible to the consumer.

(2) Written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both. Written materials shall include information on the prohibition of improper disposal of architectural paint.

(3) Advertising or other promotional materials, or both, that include references to architectural paint recycling opportunities.

(f) Any retailer may participate, on a voluntary basis, as a paint collection point pursuant to the paint stewardship program, if the retailer's paint collection location meets all of the conditions in Sections 25217.2 and 25217.2.1 of the Health and Safety Code.

48704.

(a) The department shall review the plan within 90 days of receipt, and make a determination whether or not to approve the plan. The department shall approve the plan if it provides for the establishment of a paint stewardship program that meets the requirements of Section 48703.

(b)

(1) The approved plan shall be a public record, except that financial, production, or sales data reported to the department by a manufacturer or the stewardship organization is not a public record under the California Public Records Act, as described in Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code and shall not be open to public inspection.

(2) Notwithstanding paragraph (1), the department may release a summary form of financial, production, or sales data if it does not disclose financial, production, or sales data of a manufacturer or stewardship organization.

(c) On or before July 1, 2012, or three months after a plan is approved pursuant to subdivision (a), whichever date is later, the manufacturer or stewardship organization shall implement the architectural paint stewardship program described in the approved plan.

(d) The department shall enforce this chapter.

(e)

(1) The stewardship organization shall pay the department a quarterly administrative fee pursuant to paragraph (2).

(2) The department shall impose fees in an amount that is sufficient to cover the full administrative and enforcement costs of the requirements of this chapter, including any program development costs or regulatory costs incurred by the department prior to the submittal of the stewardship plans. The stewardship organization shall pay the fee on or before the last day of the month following the end of each quarter. Fee revenues collected under this section shall only be used to administer and enforce this chapter.

(f)

(1) A civil penalty may be administratively imposed by the department on any person who violates this chapter in an amount of up to one thousand dollars ($1,000) per violation per day.

(2) A person who intentionally, knowingly, or negligently violates this chapter may be assessed a civil penalty by the department of up to ten thousand dollars ($10,000) per violation per day.

48704.1.

(a) The Architectural Paint Stewardship Account and the Architectural Paint Stewardship Penalty Subaccount are hereby established in the Integrated Waste Management Fund created pursuant to Section 40135.

(b) All fees collected by the department pursuant to this chapter shall be deposited in the Architectural Paint Stewardship Account and may be expended by the department, upon appropriation by the Legislature, to cover the department's costs to implement this chapter.

(c) All civil penalties collected pursuant to this chapter shall be deposited in the Architectural Paint Stewardship Penalty Subaccount and may be expended by the department, upon appropriation by the Legislature, to cover the department's costs to implement this chapter.

48705.

(a) On or before September 1, 2013, and each year thereafter, a manufacturer of architectural paint sold in this state shall, individually or through a representative stewardship organization, submit a report to the department

describing its architectural paint recovery efforts. At a minimum, the report shall include all of the following:

(1) The total volume of architectural paint sold in this state during the preceding fiscal year.

(2) The total volume of postconsumer architectural paint recovered in this state during the preceding fiscal year.

(3) A description of methods used to collect, transport, and process postconsumer architectural paint in this state.

(4) The total cost of implementing the architectural paint stewardship program.

(5) An evaluation of how the architectural paint stewardship program's funding mechanism operated.

(6) An independent financial audit funded from the paint stewardship assessment.

(7) Examples of educational materials that were provided to consumers the first year and any changes to those materials in subsequent years.

(b) The department shall review the annual report required pursuant to this section and within 90 days of receipt shall adopt a finding of compliance or noncompliance with this chapter.

48706.

(a) Except as provided in subdivision (c), an action solely to increase the recycling of architectural paint by a producer, stewardship organization, or retailer that affects the types or quantities being recycled, or the cost and structure of any return program, is not a violation of the statutes specified in subdivision (b).

(b) The following statutes are not violated by an action specified in subdivision (a):

(1) The Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code).

(2) The Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code).

(c) Subdivision (a) shall not apply to any agreement establishing or affecting the price of paint, except for the architectural paint stewardship assessment, or the output or production of paint, or any agreement restricting the geographic area or customers to which paint will be sold.

California Code of Regulations Section 753.1:

(a) General.

(1) The Department may deny permission to transport any species of animal or animal material into California when there may be a danger of infection from brucellosis.

(2) The provisions of this Section are in addition to other California requirements for moving cattle and bison into and within California and any requirements of the United States Department of Agriculture.

(3) The term "Health Certificate", where used in this Chapter, refers to a numbered interstate "Health Certificate", "Certificate of Veterinary Inspection", or a similar titled document that is a record of veterinary health inspection of one or more animals, issued on an official form by an accredited veterinarian from the state of origin. A Health Certificate shall be valid for 30 days following the inspection of the animals described.

(4) The term "official certificate", where used in this Chapter, shall refer to a Health Certificate, Brand Inspection Certificate, or other official inspection or movement document issued by a federal or state animal health or brand inspection representative or an accredited veterinarian at the point of origin prior to an interstate animal movement into California.

(5) Upon request by a department representative or other official, any person transporting animals into California shall produce documents for each load or part of a shipment, to prove that each animal transported, pursuant to a permit and/or Health Certificate, falls within a stated requirement or exception. Animals in any load or part of a shipment may be inspected en route or after arrival.

(6) No person(s) or entity shall receive or accept female cattle or bison transported from outside of California unless first presented with a copy of the documents required for entry. The recipient shall verify that each animal received is described on the importation documents, is identified and tested as required, and each brucellosis vaccinated animal bears a legible official brucellosis calfhood vaccination tattoo.

(7) Permits, Health Certificates, and other transportation records shall be kept by the recipient for two (2) years after the animals entered California and shall be available for examination and copying upon request by the Department.

(8) All costs of movement and post entry testing of cattle and bison shall be borne by the owner.

(9) Native animals are considered to be a group of animals under one owner, on the premises where they were born, or have been kept for at least four (4) months before shipping, provided animals have not been added to the group on the premises within the four (4) months prior to the date of shipping.

(10) Groups of animals, with no outside additions in the previous four (4) months, under common ownership or supervision, located on two or more geographically separate premises where animals from the different premises have been interchanged or had contact with each other, may be considered a "herd".

(11) Only bison originating from herds not known to be affected with brucellosis will be considered for entry into California. Test data may be required to document that the herd of origin is free from brucellosis infection. Federal brucellosis classifications for states for cattle shall not apply to bison or other animal species.

(b) Entry Permits.

(1) Permits for cattle and bison to enter California shall be obtained from the Animal Health Branch. Requests for entry permits may be made by telephone; however, written application may be required when necessary to accomplish the purposes of this section. Each entry permit shall have a unique number and shall expire 15 days after issuance, unless a special entry permit has been issued for a different period. No diversion shall be allowed from the requested destination after entry.

(2) A separate entry permit is required for each shipment containing female cattle of any age, male cattle 18 months of age and over, and bison of any age and sex, before they are transported into California. The entry permit number shall be recorded on the documents accompanying the shipment.

(3) The applicant for the entry permit shall:

(A) establish that all animals in the shipment meet California brucellosis entry requirements, and

(B) possess a properly completed Health Certificate when required.

(4) If the Department suspects or has knowledge indicating that the proposed movement might be a disease threat to California animals, or that the animals might not actually meet California entry requirements, the Department may refuse to issue a permit. The Department may require that brucellosis pre-entry testing procedures (Section 753.1(e)(1)) be completed and the results be presented to a branch brucellosis epidemiologist for evaluation before considering an entry permit. If an entry permit is issued, the Department may require, as part of the entry permit, that all of the animals in the shipment be transported to a designated inspection station immediately upon arrival in California, or held separate at their destination, for inspection by Animal Health Branch personnel. If after inspection the Department finds that all requirements for entry have been satisfied and the animals do not appear to be a disease risk and have met California entry requirements, the transporter will be given permission to deliver the animals to their destination, or they will be released if already at their destination. The entry documents will be validated as necessary.

(5) If the Department finds that the conditions of an entry permit have not been satisfied, additional proof may be required promptly from the person(s) transporting or receiving the animals. Failure to establish that the requirements for entry have been fully complied with or finding that the animals may pose a disease risk, the Department may place the animals under Hold Order until their disposition is determined and, at the expense of the owner of the animals or person in possession thereof:

(A) require vaccination or testing to remain in California, or

(B) deny permission to deliver the animals in California and require that the animals be returned to their origin, transported out of state, or be consigned to immediate slaughter.

(6) If any person has given false information to obtain an entry permit for transporting animals into California, has failed to fulfill the conditions of an entry permit, has failed to obtain an entry permit as required, or has caused brucellosis infection in California as a result of importing an infected animal, the Department may levy a penalty (Sections 9166 and 9574, Food and Agricultural Code), and/or refuse to grant future entry to such person, and/or others associated with such violations.

(7) Notification of suspension of a special entry permit may be made by personal service or by telephone with confirmation by regular mail.

(8) Requirements for movement with regular entry permits or movements associated with special entry permits may be modified in the event of an outbreak of brucellosis or other disease requiring restriction of animal movements.

(9) Most permits to allow entry of cattle into California are applied for by telephone or other electronic means accepted by the Department. A permit number, indicating approval of the application, is usually issued immediately over the telephone after entry information is gathered. The entry permit generally will be a paper or computer record for internal Animal Health Branch use and a copy will not be sent to the applicant unless specifically requested or it is needed to accompany a shipment. The information required for a regular entry permit to enter California shall include: date of issue; permit number; name of the shipper or importer; origin of the shipment; description of the animals being imported (number, type, etc.); name and mailing address of entity receiving the animals; a geographic destination if animals are not being received at the destination mailing address; purpose of the importation; name and telephone number of a contact person in California, if not the owner; name and telephone number of the person requesting the permit; the Health Certificate number, if available; name of herd veterinarian, if available; and a list of entry requirements for the type of animals entering. Additional information may be required for a special entry permit.

(c) Health Certificates.

(1) A copy of a properly completed Health Certificate with individual identification where required shall accompany each load or part of a shipment entering California containing:

(A) female dairy cattle more than four (4) months of age, and

(B) female beef cattle and all bison more than six (6) months of age, and

(C) cattle bulls more than 18 months of age, and

(D) any animal requiring a blood test prior to entry.

(2) A Health Certificate shall not be required if:

(A) all the animals in the shipment are entering for direct delivery to a slaughter establishment for immediate slaughter under official government inspection, or

(B) they have a special entry permit that exempts them from the health certificate requirement.

(3) A valid Brand Inspection Certificate may be substituted for the individual animal identification required on a Health Certificate for native cattle entering from a brucellosis Class Free State (as defined in Title 9, Code of Federal Regulations, Section 78.1, January 1, 1997 Edition) with an official brand recording agency provided all the animals in the shipment are one owner branded animals, the brand is registered to that owner, and no brucellosis blood test is required prior to entry. The Brand Inspection Certificate shall be numbered or made unique to identify it as representative only of that particular shipment. The Brand Inspection Certificate shall list the ownership brand, consignor, consignee, origin, destination, number and description of the animals, and shall be attached (stapled) to the Health Certificate. All animals in the shipment shall be officially calfhood vaccinated against brucellosis and have legible brucellosis vaccination tattoos. The owner, or the owner's designated agent, shall sign a certification on the Health Certificate indicating that:

(A) the shipment consists only of native cattle originating from a brucellosis Class Free State, and

(B) the animals in the shipment have been officially brucellosis calfhood vaccinated and have legible official brucellosis tattoos as evidence of vaccination.

(4) A valid Brand Inspection Certificate may be substituted for the individual animal identification required on a Health Certificate for native, non-test eligible (Section 752.3(e)) cattle, from a brucellosis Class A State (as defined in Title 9, Code of Federal Regulations, Section 78.1, January 1, 1997 Edition) provided the requirements of Section 753.1(c)(3) are fulfilled.

(5) The Health Certificate shall be signed by the accredited veterinarian who examined the animals in the shipment. It shall include: the permit number; a description of the animals; complete information on the consignor, consignee, origin, and destination; the federal brucellosis classification of the state of origin; purpose of the movement; and owner's certification and agreement when required in Section 753.1(f) or as specified by another disease control code or regulation. For test eligible animals, as described in Section 753.1(e), the description shall

include individual animal identification with the official eartag number, a representation of the brucellosis vaccination tattoo present, brucellosis test date and results. A copy of the official brucellosis test record with a description of each animal, its eartag number, its brucellosis vaccination tattoo, and blood test results may be attached to each copy of the Health Certificate instead of transferring that information onto the certificate. Brucellosis vaccinated animals that are exempt from testing requirements, and are entering California for movement and sale within the State shall have the presence of vaccination and legible tattoos certified by the owner. The Health Certificate, with attachments, shall be available for examination en route and after arrival in California. A copy of the completed Health Certificate shall be sent to the California State Veterinarian's office within 15 days of examination. Purebred registered cattle entering California, if not utilizing an official vaccination eartag and tattoo for identification, may be identified by a registration ear tattoo and their official brucellosis calfhood vaccination tattoo, or by another method of permanent identification as requested by the owner and approved by the Department.

(6) The examining accredited veterinarian shall indicate on the Health Certificate that each animal in the shipment meets California entry requirements.

(7) It may be necessary to obtain a Health Certificate for entry into California because of a disease condition in another state, even though the animals are exempt from obtaining a Health Certificate by brucellosis regulations.

(d) Vaccination Requirements.

(1) Official brucellosis calfhood vaccination, indicated by the presence of a legible official calfhood vaccination tattoo as evidence of the vaccination, is required for entry of each:

(A) dairy breed female more than four (4) months of age.

(B) beef breed female more than 12 months of age and requested of each beef breed female more than six (6) months of age.

(2) Non-brucellosis vaccinated female:

(A) dairy and beef breed calves of brucellosis vaccination age will be allowed to enter California if they meet the requirements of a prior special entry permit to be vaccinated against brucellosis on arrival.

(B) dairy breed cattle over eight (8) months of age, and beef breed cattle over 12 months of age shall not be eligible for entry into California unless entering:

1. with a special entry permit, or

2. for immediate slaughter at a slaughter establishment under official government inspection.

(3) Brucellosis vaccination is not required for entry of:

(A) dairy breed female calves less than four (4) months of age.

(B) beef breed female calves less than six (6) months of age.

(C) bison, steers, bulls, and identified spayed female cattle.

(e) Test Requirements.

(1) Blood for pre-entry testing shall be collected within 30 days before entry and tested by a laboratory approved for brucellosis testing by federal or state officials. An additional signed statement must be included on the Health Certificate that explains how the test results were verified to represent each animal in the shipment when the blood was not collected and submitted to the laboratory by the veterinarian issuing the Health Certificate.

(2) No animals will be allowed to enter California if they are part of a lot or herd in which a reactor has been found.

(3) Cattle from non-Class Free States and cattle from a Class Free State that are not native to that state (Section 753.1(a)(9)) must have a negative brucellosis blood test record prior to entry if they are:

(A) non-brucellosis vaccinated female calves of brucellosis vaccination age entering under a special entry permit to be vaccinated on arrival, or

(B) brucellosis vaccinated dairy breed females 18 months of age and over, or

(C) brucellosis vaccinated beef breed females 24 months of age and over, or

(D) parturient (springers) or post-parturient of any age, or

(E) cattle bulls 18 months of age and over, or

(F) beef heifers six (6) months of age and over not vaccinated against brucellosis.

(4) Bison (except steers and identified spayed heifers) from any state must have a negative brucellosis blood test record prior to entry if they are:

(A) non-brucellosis vaccinated female calves of brucellosis vaccination age entering under a special entry permit to be vaccinated on arrival, or

(B) six (6) months of age and over and not vaccinated against brucellosis, or

(C) brucellosis vaccinated females 24 months of age and over, or

(D) parturient (springers) or post-parturient of any age.

(5) Non-brucellosis vaccinated female animals with a special entry permit from any class state must be brucellosis test negative prior to entry if they are:

(A) registered cattle entering for preserving or developing bloodlines.

(B) cattle or bison entering a registered feedlot included in a registry of currently approved feedlots maintained by the Department for feeding prior to slaughter.

(6) The test requirements of this Section do not apply to:

(A) cattle native to brucellosis Class Free States that are:

1. non-brucellosis vaccinated female calves of brucellosis vaccination age entering under a special entry permit to be brucellosis vaccinated on arrival, or

2. officially calfhood brucellosis vaccinated female cattle of any age with legible official brucellosis vaccination tattoos, or

3. bulls.

(B) cattle and bison irrespective of the status of the state of origin transported into California that are:

1. for direct delivery to a slaughter establishment for immediate slaughter under official government inspection.

2. dairy breed female calves less than four (4) months of age.

3. brucellosis vaccinated dairy breed females under 18 months of age.

4. beef breed female calves less than six (6) months of age.

5. brucellosis vaccinated beef breed females under 24 months of age.

6. cattle bulls less than 18 months of age, steers, and identified spayed females.

7. cattle and bison from current Certified Brucellosis-Free Herds. The herd number and the date of the current test shall be recorded on the Health Certificate.

8. cattle consigned directly to a Specifically Approved Stockyard. There shall be no movement out of a Specifically Approved Stockyard except to slaughter, or to leave California, unless the animals meet all California entry requirements.

9. officially brucellosis calfhood vaccinated dairy breed females returning with a special entry permit after feeding another state.

(f) Special Entry Permits.

(1) Dairy heifers, officially brucellosis calfhood vaccinated originating in California, feeding in a Class Free State for a period of time, and returning to the property of the same owner in California, may be granted a special entry permit for the return of the vaccinated dairy heifers to California, valid for 15 days, to return to California without a brucellosis blood test if the owner, or designated agent of the owner, signs and dates a form containing the following certification, agreement, and information:

(A) certifying:

1. to continuous ownership of the heifers prior to leaving and while out of California.

2. that cattle from states other than California have not been added to the group while out of California.

3. that the returning heifers have not commingled with another owner's cattle during transportation and while out of California.

4. that all animals in the shipment originated in California and were officially brucellosis calfhood vaccinated at the prescribed age and have legible official brucellosis tattoos.

5. that the heifers have not left the Class Free State where they were feeding.

6. to examination of each animal in the shipment for health and identification purposes within the 30 days prior to return to California and certifying that as a result of that examination that:

a. each animal is apparently healthy;

b. a legible recording has been made of each animal's individual identification, both official and herd, a representation of the official brucellosis tattoo, breed, and approximate age, on a list which contains the same information about all of the animals in the shipment.

(B) agreeing to:

1. complete the special entry permit form or obtain a Health Certificate.

2. obtain a special entry permit number for each shipment (for either a special entry permit or a Health Certificate).

3. send the original signed special entry permit or a Health Certificate (with the permit number recorded and the list of animals included in the shipment stapled to either form), to the State Veterinarian's office in California on departure for California.

4. make a separate copy of the completed special entry permit or the Health Certificate to accompany each load or part of the shipment and to present it to any state regulatory official on their request.

5. deliver a copy of the completed special entry permit or the Health Certificate (with a list of heifers in the shipment attached) at the destination.

6. present some or all of the heifers and/or the entry documents for inspection at a reasonable time after arrival to validate compliance with this regulation, if requested by Animal Health Branch personnel.

7. keep an individual animal identification record of non-California heifers purchased and brought into California before being transported out of California for feeding under this special entry permit. The purchasers of the out-of-state

heifers shall maintain sufficient animal identification to trace the purchases back to their origin.

The owner is responsible for the accuracy of the certifications and the attached animal identification list which becomes part of the special entry permit or Health Certificate. This special entry permit form shall contain: the signature of the owner or the owner's agent; the printed name of the person signing the special entry permit form and the address and telephone number of the owner; an accurate description of the destination with name, geographic location, mailing address with county, and name and telephone number of the manager or other contact person at the destination. If the special entry permit is being requested by telephone and the request is approved, the permit number and expiration date shall be recorded in the appropriate location on the form before making copies for the transport vehicles. If the special entry permit is mailed or faxed for approval, a copy will be returned by the same method, if approved.

If the owner chooses to get a Health Certificate with individual identification instead of using this California special entry permit form, the certifications (A)1 through 5, and agreements (B)3 through 7, in this Subsection shall be signed and included as part of the Health Certificate along with the notation "Dairy heifer brucellosis vaccinates returning to California."

It is the intent of this special entry permit to trace the movement of dairy animals as accurately as possible, and should a brucellosis reactor or suspect be found, to be able to trace them to their herd of vaccination and origin.

(2) The owner of an officially brucellosis calfhood vaccinated beef breeding herd may be issued a Pasture to Pasture Permit for a single seasonal movement (to and return within eight (8) months) between pastures under the control of the same owner in California and a Class Free State following certification by the state of origin and approval of the owner's written application by California. Owners requesting permission to enter California for pasture, or return to California after out of state pasture under a Pasture to Pasture Permit, shall utilize the California Pasture to Pasture Permit for the movement, even if it is in addition to another state's permit. The transmission of applications and approvals by mail or fax is permissible.

(A) A signed, approved permit shall contain the expiration date and permit number as furnished by the destination state.

(B) The applicant shall furnish the following information: state of origin and destination; number of animals by age groups (females over two (2) years old, heifers between six (6) months and 24 months old, adult bulls, steers, calves under six (6) months old, horses); brand and location; accurate description of origin and destination premises by: premises name; geographic location; mailing address including the city, state, zip code, and county; name and telephone number of premises owner or manager and any other contact information available; name and telephone number of veterinarians servicing the herd; number of years the herd has moved to described premises; fenced premises (Y/N); commingling with cattle owner by others (Y/N); and names of other owners commingling.

(C) The applicant shall acknowledge that Pasture to Pasture Permit is for one pasture season for the described cattle, time, and premises, and that no diversion of cattle from the described premises will be allowed without prior permission of the State Veterinarian's office where cattle are on pasture, and then, only due to an environmental emergency.

(D) The applicant shall certify that:

1. the animals entering under the permit are from a beef breeding herd established more than six (6) months in the Class Free State of origin;

2. it will be established, by brand or health certificate obtained within the 30 days prior to a load or part of a shipment entering or returning to California, that the cattle have healed brands (brands that appear to have been applied at least four (4) months prior to movement) or other identification officially registered to the owner;

3. no trader or recently assembled cattle are in the origin herd or the animals moving;

4. all female cattle over six (6) months of age entering or returning to California are or will be officially brucellosis calfhood vaccinated and bear or will bear legible official brucellosis tattoos as evidence of the vaccination.

(E) The purchase or addition of native cattle originating in the Class Free State destination state will be allowed if the owner certifies that:

1. the purchased or added cattle are native to the destination state, have been officially brucellosis calfhood vaccinated, and have legible official brucellosis vaccination tattoos, and

2. the California State Veterinarian's office is notified by mail or fax of the purchase or addition of animals, by number and type, in the destination state prior to returning at the end of the pasture season.

(F) Before California can approve entry with a Pasture to Pasture Permit, an animal health official of the state of origin shall certify that the herd needing permission to enter California for pasture is an established beef breeding herd that is current with its brucellosis calfhood vaccinations and is not known to be affected with or exposed to brucellosis. After receiving this certification, the Department shall evaluate the entries on the permit request. If it appears that there will be no brucellosis danger to California animals and that the applicant will implement the permit requirements, the permit may be approved by a representative of the Animal Health Branch.

(G) The owner, or owner's agent, of cattle that have received a Pasture to Pasture Permit to leave California for pasture and return shall:

1. enter the estimated date of return to California and any animal purchase or animal addition information on the permit as indicated.

2. forward a copy of the permit with the return information to the State Veterinarian of California by mail or fax within the 15 days prior to the date of returning the first load or part of a shipment of cattle.

(H) Cattle moving with an approved Pasture to Pasture Permit are exempt from brucellosis test and individual identification requirements associated with a Health Certificate as long as the owner remains in compliance with the current approved Pasture to Pasture permit and there is no suspicion of brucellosis infection in the herd. An official certificate, in addition to the valid permit, is required to be obtained for all cattle within the 30 days prior to entering California. Copies of the official certificate and the Pasture to Pasture Permit shall accompany each load or part of a shipment of cattle entering California.

(3) A special entry permit may be issued for entry of non-brucellosis vaccinated brucellosis, test negative, purebred registered dairy or beef breed cattle, with breed association individual identification, for preserving or developing bloodlines. A copy of the registration papers, along with side-view photographs suitable for identification purposes, a drawing of the registration ear tattoo, or a description of other registration mark or identifier, may be required to be forwarded to the Animal Health Branch, before a special entry permit can be considered. The cattle shall meet all other entry identification and negative test

requirements. Animals admitted under this provision shall be maintained under a permanent Hold Order. If it appears that there will be no disease risk to a non-brucellosis vaccinated animal at an exhibition and the exhibition allows their entry, the Department may give written permission to move within California to be exhibited. A Permit to Move may be issued for movement: for exhibition, to another premises, to go to slaughter, or to leave the State.

(4) A special entry permit may be issued for entry of brucellosis vaccination age, non-brucellosis vaccinated calves, native to their state of origin, to be brucellosis vaccinated on arrival by a program cooperator (a person who by past favorable interaction with the brucellosis program, or by industry reputation, it is felt will implement the requirements of the special permit). If the cooperator and the vaccination premises appear to be satisfactory to the destination Animal Health Branch District, Animal Health Headquarters may issue a permit and calves will be allowed to enter from:

(A) Class Free States without a negative brucellosis test, or

(B) non-Class Free States with a negative brucellosis test.

(5) Following a signed interstate feeder heifer agreement between the State Veterinarians of a Class Free State of origin and California, a special Beef Feeder Heifer Permit, valid for up to one year, may be issued to an owner to import, for feeding or pasture purposes for a period of up to eight (8) months, apparently healthy female beef breed heifers under the age of 24 months that have been officially calfhood vaccinated against brucellosis, providing the owner complies with the following conditions:

(A) At least 15 days before the first expected entry, or expiration of a prior Beef Feeder Heifer Permit, the owner shall complete a written application for a special Beef Feeder Heifer Permit and obtain the approval of a California Animal Health Branch Staff Veterinarian and the acknowledgment of the an animal health staff member of the Class Free origin state. The application for the Beef Feeder Heifer Permit, when approved, will serve as the permit and shall contain the following information: date of application, permit number issued, expiration date of the permit, and the applicants name. Space will be provided on the application for approval by a California Animal Health Staff Veterinarian and acknowledgment of an animal health official of the origin state.

1. The owner, or agent of the owner, shall certify on each Beef Feeder Entry Form that all the animals in that shipment:

a. are apparently healthy.

b. are beef breed heifers under 24 months of age.

c. originate from a brucellosis Class Free State.

d. are officially calfhood vaccinated against brucellosis.

e. have legible official brucellosis vaccination tattoos.

f. have not had any contact with cattle of Mexican origin.

2. In addition, the applicant shall agree to:

a. complete a Beef Feeder Heifer Entry Form for each shipment of heifers entering California.

b. send (mail or fax) a copy of the completed entry form to the State Veterinarian of California and the origin state within 15 days prior to the expected date of entry of each shipment.

c. provide a copy of the completed entry form to the driver of each load of heifers in the shipment and instruct the driver to present the copy to government officials for examination when requested.

d. notify the local Animal Health District Office of movement to: another previously registered premises, another state, into a trade channel, sale to a private buyer, or to slaughter.

e. maintain records for tracing of the origin and disposition of the heifers for two (2) years for inspection and copying by Animal Health representatives.

f. within 30 days after the completion of the feeding period, notify the local Animal Health District Office of the number of heifers disposed of by:

1. slaughter.

2. addition to the owner's breeding herd.

3. movement to an identified state.

4. movement into an identified trade channel.

5. sale to an identified private buyer.

6. other.

The applicant shall print the owner's personal or business name, furnish complete address with telephone and fax numbers, and shall sign the certification and agreement. The application shall contain information on how to submit an application for premises registration.

(B) A copy of a properly completed Beef Feeder Heifer Entry Form shall accompany each load or part of a shipment of animals into California with the following information:

1. The entry date, permit number and its expiration date, and the origin state.

2. The owner's (or owner's agent) certification that all animals in the shipment are apparently healthy beef breed heifers under 24 months of age, originate from a Class Free State, have been officially calfhood vaccinated against brucellosis, bear legible official brucellosis tattoos, and have had no contact with any cattle that originated in Mexico. If the certification is signed by an agent of the owner, the agent's name, address, and telephone number shall by printed on the entry form. Owners, or owners' agents, may be required to present evidence that the animals in a shipment meet the entry requirements of this paragraph.

3. The name, address, and telephone number of the person responsible for managing the heifers in California.

4. The identification of the origin of the cattle by location or premises name and county and destination premises by number, name, and county.

5. The number and physical description of the heifers by age, weight, breed, and brand.

6. An indication of whether purchase was at a livestock marketing facility or by private treaty if heifers were purchased for feeding or pasture purposes and are not native to the state of origin of the shipment. If the heifers are not native to the shipment origin state, the source states shall be indicated. The states where the heifers were purchased must be Class Free. Purchaser must maintain records of purchases, for inspection and copying by department representatives, for two (2) years following the transaction.

7. "Blank and completed Beef Feeder Heifer Entry Forms may be copied as needed for movement of animals."

(C) The destination premises shall be registered by the Animal Health Branch District containing the premises prior to departure for California. Registration shall be accomplished by submitting a completed registration form by mail, fax, or telephone to the local Animal Health Branch District Office or Animal Health Branch Headquarters of the Department in Sacramento. Issuing of a premises number will indicate successful registration. Once a premises is registered, it may be used until expiration of the registration, by any Beef Feeder Heifer permit holder. Premises may be approved for up to two (2) calendar years, with expiration on December 31 of the second year, in advance of anticipated entries and later movement. The Beef Feeder Heifer Premises Registration form, in addition to information on how to and where to obtain a registration form, shall contain:

1. The date of the registration, the premises number, expiration date, county of the premises, and the Animal Health District of the premises.

2. Name of the applicant, printed legibly; premises name; county name; type of premises; geographic location; and property owner's name, mailing address, and telephone number.

3. Name, address, and telephone number of the person managing the premises, if not the owner.

4. Signer's name printed legibly and signature of the applicant.

5. If the registration is signed by an agent of the owner or applicant, the person's name, address, and telephone number shall be printed legibly on the registration.

6. "Blank Beef Feeder Heifer Premises Registration forms may be copied as needed for submission for registration of premises."

(D) During and at the end of the feeding or pasture period, the heifers may be moved:

1. To slaughter.

2. Following notification of the local Animal Health District Office: to another registered premises, into the owner's breeding herd, out of state, into a trade channel, or sold to a private buyer.

3. Within 30 days after the completion of the feeding period the permit holder shall notify the local Animal Health District office of the number of heifers in each shipment disposed by:

a. slaughter.

b. addition to the owner's breeding herd.

c. movement to an identified state.

d. movement into an identified trade channel.

e. sale to an identified private buyer.

f. other.

(6) Animals, from any state, not vaccinated against brucellosis, with a negative brucellosis entry blood test, and a Health Certificate with individual animal identification, may be issued a special entry permit to enter a registered feedlot (not pasture) included in a registry of currently approved feedlots maintained by the Department for feeding for up to six (6) months before slaughter. They will be maintained under a Hold Order until slaughtered at an establishment under official government inspection.

(7) Animals entering California for direct delivery to an establishment under official government inspection for immediate slaughter must be sufficiently identified to ensure tracing to the farm or ranch of origin. They may enter with a Brand Inspection Certificate instead of a Health Certificate. A properly placed United States Department of Agriculture backtag is acceptable identification in place of an eartag if the backtag number is listed and the list is attached (stapled) to an official certificate. If a backtag is used as identification, the party utilizing it must be able to trace the animal in question back to its herd of origin and it must be the last identification applied before entry and moving to slaughter. A copy of the certificate, with attachments, shall be kept for at least two (2) years by the shipper. All certificates shall be made available for examination when requested by a department representative.

(g) Exceptions. Any exceptions to the interstate movement section of this regulation shall have approval by the Department prior to movement. All exceptions shall be evaluated on a case-by-case basis and the following factors, at a minimum, shall be considered before approval of any exceptions:

(1) Possible exposure of California livestock to brucellosis.

(2) Welfare of out of state livestock.

(3) Cost to the Department for personnel to monitor the exception.

(4) Reaction of the public and/or the livestock industry to approval of the exception.

California Code of Regulations Section 758:

(a) All sexually intact cattle regardless of age shall have the following:

(1) An Interstate Livestock Entry Permit and

(2) A Certificate of Veterinary Inspection.

(b) All breeds of cattle, bison, goats and cervids, of any age and sex, identified as originating from or documented as having been in or at a location, state, territory, or foreign country that the State Veterinarian determines to be a threat for introducing bovine tuberculosis into California or that is documented as having a significant tuberculosis infection and entering California may be required to meet the following additional requirements:

(1) All animals more than six (6) months of age must be negative to an official tuberculosis test completed within 60 days prior to entering California, or

(2) Animals must have been part of a whole herd negative official tuberculin test (all animals more than six (6) months of age tuberculosis tested and all negative) within 12 months before departure, and have a negative official tuberculin test within 60 days before departure for California (90 days for cervids). If an animal was not tested at the last whole herd tuberculin test, documents must accompany the animal showing it: had a negative official tuberculin test before entering the herd and within 12 months of departure for California, or it was born into the herd, and

(3) All imported animals shall be quarantined and held at their destination until an official tuberculin test in California 61 to 120 days after their last test before entry (91 to 120 days for cervids) has been completed. Animals may move from that location only under written directions from the Animal Health Branch. If a suspect or a reactor is found in a shipment, the whole herd at destination will be quarantined until a designated tuberculosis epidemiologist determines the final

classification. No indemnity shall be paid for imported animals classified as suspects or reactors.

(c) Individually identified animals moving directly to an officially inspected slaughter establishment shall be exempt from entry test requirements.

(d) Animals exposed to or originating from any quarantined herd, premises, county, zone, or area shall not enter California.

(e) The Department may require mitigation of risk factors OR deny the entry into California of any species of animal or any animal material if there may be a possibility of transmission of bovine tuberculosis infection.

California Code of Regulations Section 796.4:

(a) Swine imported from any state for purposes other than slaughter must comply with the most stringent interstate movement requirements applicable to any other swine in the shipment.

(b) Swine imported into California for any purpose, except slaughter, shall have:

(1) Certificate of Veterinary Inspection; and

(2) Official identification; and

(3) Interstate Livestock Entry Permit; and

(A) A regular Interstate Livestock Entry Permit will not be granted for swine vaccinated for pseudorabies. However, the State Veterinarian may grant a special permit, on a case-by-case basis, with specific limitations necessary to prevent the spread of pseudorabies from such swine. A special permit application must be submitted and include all information required for a regular permit plus official identification for each animal in the shipment, exposure history, which of the animals have been vaccinated, and the vaccine type, brand, and date of vaccination.

(4) a negative test result to an official pseudorabies test within 30 days prior to entry. Persons receiving swine must have documentation issued by the accredited veterinarian at the point of origin, showing each animal was negative to the official pseudorabies test within 30 days prior to entry.

(c) Swine shall be quarantined and isolated pursuant to Food and Agricultural Code section 9562 at destination pending the results of an official pseudorabies retest conducted 30 to 60 days after entering California.

(1) Swine may be released from quarantine if negative to the official pseudorabies retest or when slaughtered in a state or federally inspected slaughter establishment.

(d) Swine may be exempt from the test, quarantine and isolation, and retest requirements when:

(1) Native to and shipped directly from a state classified as Stage IV or V by the USDA and not exposed to swine from a state classified below Stage IV by the USDA.

(e) Additional testing may be required for any pseudorabies positive, suspect or exposed animals in or separate from the shipment.

California Code of Regulations Section 796.5:

(a) Swine imported from any state for purposes other than slaughter must comply with the most stringent interstate movement requirements applicable to any other swine in the shipment.

(b) Swine imported into California for any purpose, except slaughter, shall have:

(1) Certificate of Veterinary Inspection; and

(2) Interstate Livestock Entry Permit; and

(3) Official identification; and

(4) for sexually intact swine over four months of age, a negative test result to an official brucellosis test within 30 days prior to entry. Persons receiving swine must have documentation issued by the accredited veterinarian at the point of origin, showing each animal was negative to the official brucellosis test within 30 days prior to entry.

(c) Swine shall be quarantined and isolated pursuant to Food and Agricultural Code section 9562 at destination pending the results of an official brucellosis retest conducted 30 to 60 days after entering California.

(1) Swine may be released from quarantine if negative to the official brucellosis retest or when slaughtered in a state or federally inspected slaughter establishment.

(d) Swine may be exempt from the test, quarantine and isolation, and retest requirements when:

(1) Native to and shipped directly from a validated brucellosis-free herd or validated brucellosis-free state or region classified by the USDA, and not exposed to or commingled with swine from a state that is not classified as free from swine brucellosis by the USDA. Verification that the animals originated from a validated brucellosis-free herd or validated brucellosis-free state or region shall be stated on the Certificate of Veterinary Inspection.

(e) Additional testing may be required for any brucellosis positive, suspect or exposed animals in or separate from the shipment.

California Code of Regulations Section 820.3:

(a) Bulls 18 months of age and over shall have all of the following:

(1) Official individual identification;

(2) An Interstate Livestock Entry Permit;

(3) Negative trichomonosis test results within 60 days prior to entry into California; and,

(4) A Certificate of Veterinary Inspection which states:

(A) The bulls represented on this Certificate of Veterinary Inspection have been tested for and found to be negative for trichomonosis pursuant to subsection (a)(3) above and have been confined and have not had sexual contact with females since their last negative test; and

(B) Trichomonosis has not been diagnosed in the herd of origin within the past 24 months.

(b) Any bull originating from a herd in which trichomonosis has been diagnosed within the past 24 months shall have all of the following:

(1) One (1) negative real-time PCR test or three (3) consecutive negative trichomonosis culture tests conducted on specimens collected at least seven (7)

days apart, but not more than 28 days apart, with the last test conducted within 60 days prior to entry; and

(2) A Certificate of Veterinary Inspection which states that the requirements set forth in subsection (b)(1) above have been met.

(c) Breeding bulls entering California as part of a herd that has been authorized entry into California via a Pasture to Pasture permit pursuant to section 753.1(f)(2)(A) through (H) of Title 3 of the California Code of Regulations, require one negative trichomonosis test within the 12 months prior to entry. The Pasture to Pasture permit shall include the date and test results or a copy of the test record may be attached to the permit, and the name and telephone number of the testing veterinarian.

(d) Bulls may be exempt from the trichomonosis test requirements for entry into California under any one or all of the following conditions:

(1) Used solely for exhibition purposes and remains under confinement at the location of the exhibition without having access to or allowed to commingle with sexually mature female cattle; or

(2) Used solely for artificial insemination using semen extension and preservation protocols that meet Certified Semen Services standards; or

(3) Consigned directly to slaughter without unloading prior to the arrival at slaughter plant.

California Code of Regulations Section 17944:

(a) On or after January 1, 1995, all rigid plastic packaging containers, except a rigid plastic packaging container that is exempt under Section 17946.5 of this Article, sold or offered for sale in California must meet one of the following criteria:

(1) Be made from at least 25 percent postconsumer material and remain in compliance with applicable state and federal regulations, including those adopted by the United States Food and Drug Administration. If it is technologically infeasible for a rigid plastic packaging container to meet this requirement, such a container must comply with another compliance option within this section.

(2) Be recycled at a 45 percent recycling rate if a product-associated rigid plastic packaging container, particular-type rigid plastic packaging container, or a single resin type rigid plastic packaging container.

(3) Be a reusable rigid plastic packaging container or a refillable rigid plastic packaging container.

(4) Be a source reduced rigid plastic packaging container.

(5) Be a rigid plastic packaging container which contains floral preservative and is subsequently reused by the floral industry for at least two years. This compliance option is only available for rigid plastic packaging containers used by the floral industry in California. Similar rigid plastic packaging containers sold to nurseries, landscapers, retail stores, and other outlets that are not wholesale or retail flower sellers or growers do not qualify for this compliance option.

(b) A product manufacturer may achieve compliance based on averaging. Averages may be calculated using either data specific to rigid plastic packaging containers sold and/or recycled in California or data on rigid plastic packaging containers sold and/or recycled nationwide. Averages shall be calculated for postconsumer material using the formula in Section 17945.5(b)(2), for source reduction using the formulas in Section 17945.5(d)(4), for reuse using the formula in Section 17945.5(e)(2), and for refill using the formula in Section 17945.5(f)(2). Averages may be based on the product manufacturer's entire product line or separated into product sub-lines. If averages are used to achieve compliance, all rigid plastic packaging containers must be accounted for in the calculation or must comply through another compliance option.

California Assembly Bill No. 2347 (2008), Section 1:[1]

SECTION 1.

The Legislature finds and declares all of the following:

(a) Mercury that is released into the atmosphere can be transported long distances and deposited in aquatic ecosystems, where it is methylated to methylmercury, the organic and most toxic form of mercury.

[1] Cited in Alameda County's Brief as Recitals to California Health & Safety Code Section 25214.8.10 *et seq.*

(b) Methylmercury bioaccumulates and biomagnifies in animals, including fish and humans.

(c) The March 2007 report of the Office of Environmental Health Hazard Assessment stated that fish consumption advisories exist in about 40 states, including, within California, for the San Francisco Bay and Delta, Tomales Bay, and eight other county water bodies, and more locations may be included as more fish and water bodies are tested.

(d) Methylmercury is a known neurotoxin to which the human fetus is very sensitive.

(e) The federal Centers for Disease Control and Prevention estimate that between 300,000 and 630,000 infants are born in the United States each year with mercury levels that are associated, at later ages, with the loss of IQ.

(f) New evidence indicates that methylmercury exposure may increase the risk of cardiovascular disease in humans, especially adult men.

(g) According to a 2004 study by the federal Environmental Protection Agency, more than 10 percent of the estimated mercury reservoir still currently in use in the United States resides in mercury-added thermostats.

(h) Decreases in local and regional sources of mercury emissions have been shown to lead to decreases in mercury levels in fish and wildlife.

(i) As of January 1, 2006, state law banned the sale of new mercury-added thermostats for most uses, but the long lifetime of thermostats means that many of them are still in use.

(j) State law bans the disposal of mercury-added thermostats in solid waste landfills, but according to an estimate by the Department of Toxic Substances Control, less than 5 percent of the mercury-added thermostats removed from buildings in the state are turned in to the Thermostat Recycling Corporation (TRC) collection program.

(k) In 1998, thermostat makers General Electric, Honeywell, and White Rodgers, established the TRC to implement a program for collecting used mercury-added thermostats. Under the TRC program, thermostat wholesalers and contractors volunteer to collect thermostats from heating, ventilating, and air-conditioning contractors, and the general public. In 2007, the manufacturer

Nordyne joined the program and the TRC expanded its voluntary program to household hazardous waste facilities.

(l) The California Integrated Waste Management Board adopted an Overall Framework for an Extended Producer Responsibility (EPR) guidance document as a policy priority in September 2007 and approved refinements in January 2008.

(m) The EPR framework recognizes that the responsibility for the end-of-life management of discarded products and materials rests primarily with the producers, thereby incorporating costs of product collection, recycling, and disposal into the total product costs so as to have a reduced impact on human health and the environment.

(n) Producers that historically manufactured, branded, and sold mercury-added thermostats in California before 2006 have a responsibility to collect out-of-service mercury-added thermostats and ensure that they are properly handled and recycled.

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